

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
24 December 2003 (24.12.2003)

PCT

(10) International Publication Number  
**WO 03/105667 A2**

- (51) International Patent Classification<sup>7</sup>: **A61B**
- (21) International Application Number: PCT/US03/18749
- (22) International Filing Date: 12 June 2003 (12.06.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
- |            |                             |    |
|------------|-----------------------------|----|
| 60/388,250 | 12 June 2002 (12.06.2002)   | US |
| 10/232,753 | 30 August 2002 (30.08.2002) | US |
| 10/461,861 | 12 June 2003 (12.06.2003)   | US |
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(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

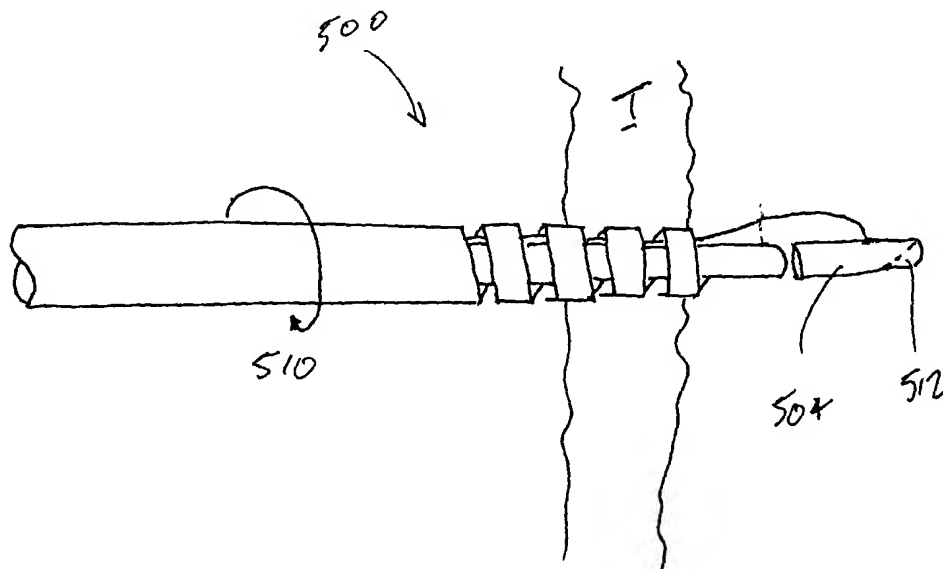
(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

— *without international search report and to be republished upon receipt of that report*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: METHOD AND APPARATUS FOR TISSUE CONNECTION



(57) Abstract: A tissue connecting device is provided. The device comprise an elongate delivery device having a lumen, a proximal end, and a distal end. The distal end is configured to engage tissue and advance said device into tissue. At least one anchor deliverable through a lumen of the elongate delivery device. The distal end of the device may be designed to engage tissue upon rotation of the device about its longitudinal axis.



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## 5           **METHOD AND APPARATUS FOR TISSUE CONNECTION**

### BACKGROUND OF THE INVENTION

#### Field of the Invention

10           This invention relates generally to medical devices, and their methods of use, and more particularly to devices, and methods of use, utilized for the repair and reconnection of various tissues of the body. The present invention may be useful in a variety of applications including but not limited to minimally invasive devices and methods for repair or reshaping of improperly functioning heart valves or heart tissue.

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#### Description of Related Art

Bringing together tissues in closer proximity to one another is a typical means for closing wounds such as catheter puncture sites during percutaneous procedures (angioplasty, stenting, endograft procedures and the like), as well as in stomach stapling  
20   for the morbidly obese, gastrostomy placement, etc. Although these procedures all may benefit from the inventions described herein, one particularly useful and immediate benefit for these devices, methods and systems is in the bringing together, or coaptation, of heart valve leaflets so that they close properly against the relatively high pressures during the contraction of the heart muscle so as to improve the pumping efficiency of the  
25   heart muscle. Furthermore, the present invention additionally provides new and novel devices, methods and systems for the percutaneous endovascular repair of the valves of the heart and for their modification and subsequent improvement in cardiac valve function.

30           Mitral valve regurgitation is a condition in which the leaflets of the heart valve do not properly close during contraction (systole) of the heart. This permits blood to flow in a retrograde fashion from the ventricle of the heart back into the atrium of the heart. The pumping efficiency of the heart is compromised and the result, if left unchecked, can be

progressive heart failure resulting in extreme fatigue or worse and the inability of the patient to lead a normal life.

Although there are numerous reasons for damage to the valves of the heart, the typical treatment is often surgery. During surgical repair of the valves, the chest is usually opened, at least in part, to allow enough room for the surgeon to perform a repair or replacement of the damaged valve. This usually requires that the patient be placed on a bypass machine to pump the blood while the surgeon operates on the stopped heart muscle. For obvious reasons, this can be very traumatic on the patient and recovery may take many months. Additionally, surgery may not be an option for some patients due to limited possibility for recovery, concurrent disease, or age.

For these reasons, it would be desirable to provide an alternative to open heart surgery to modify, repair or replace a damaged heart valve without requiring the patient's chest to be opened and/or the patient placed on bypass during the procedure.

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## SUMMARY OF THE INVENTION

The present invention provides new and novel devices, methods and systems for the repair of the valves and for their modification and subsequent improvement in valve function. More specifically, in some embodiments, the present invention achieves these repairs using percutaneous endovascular techniques that minimize trauma to the patient and provide reduced recovery time and recovery cost.

In one aspect of the present invention, a tissue connecting device is provided. The device comprise an elongate delivery device having a lumen, a proximal end, and a distal end. The distal end is configured to engage tissue and advance said device into tissue. At least one anchor deliverable through a lumen of the elongate delivery device. The distal end of the device may be designed to engage tissue upon rotation of the device about its longitudinal axis.

In a still further aspect of the present invention, a kit is provided for delivering a tissue connection device to a valve having an annulus and a plurality of leaflets. The kit may include an elongate member having a first substantially linear configuration when engaged with an elongate delivery device and a second substantially circular configuration defining a first support ring and a second support ring when the member disengages from the delivery device. The kit may further include instructions for use

describing a method for connecting the elongate member to the valve and a package for holding the elongate member and the instructions for use.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

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### BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is perspective view of an annular support device.

Figures 2-5 illustrate the delivery of the device of Figure 1 to a treatment site.

Figure 6 shows another embodiment of present invention for use with a  
10 straightening mandrel.

Figures 7A and 7B show cross-sectional views of interaction between two support rings to engage tissue therebetween.

Figure 8A and 8B are top and side views of another annular support device.

Figure 9 shows the device of Figure 1 penetrating tissue.

15 Figures 10A-10C show the use of sutures on annular support rings in accordance to the present invention.

Figure 11 shows the attachment of sutures to a support ring in a linear configuration.

Figures 12-13B show various geometries of the support ring.

20 Figures 14A-14D illustrate the use of a support ring and sutures at a tissue site.

Figures 15A-20 show embodiments of the present invention using separable clamping portions.

Figures 21-27D illustrate varying geometries of leaflet clamps for use with the present invention.

25 Figures 28-30 show the delivery of an apparatus according to the present invention with deflectable leaflet clamps.

Figures 31-35 illustrate positioning of delivery devices to reach a treatment site in the heart.

Figure 36 shows a kit containing an annular support ring and accessories.

30 Figure 37 shows a suture coupled to a support member.

Figures 38-40 show clamps for used with shaped guide wires.

Figures 41-43 show delivery of anchors into tissue.

Figures 44-52 show additional techniques for delivering support devices to tissue.



Figures 53-60 show various anchor embodiments according to the present invention.

Figures 61-73 show various anchor and delivery devices for use in piercing tissue.

Figures 74-77 show additional uses of embodiments of the present invention.

5       Figures 78-86 show still further embodiments of delivery devices and anchors according to the present invention.

#### DESCRIPTION OF THE SPECIFIC EMBODIMENTS

10       It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed. It may be noted that, as used in the specification and the appended claims, the singular forms “a”, “an” and “the” include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to “a material” may include mixtures of materials, reference to “a chamber” may include multiple chambers, and the  
15       like. References cited herein are hereby incorporated by reference in their entirety, except to the extent that they conflict with teachings explicitly set forth in this specification.

In this specification and in the claims which follow, reference will be made to a number of terms which shall be defined to have the following meanings:

20       “Optional” or “optionally” means that the subsequently described circumstance may or may not occur, so that the description includes instances where the circumstance occurs and instances where it does not. For example, if a device optionally contains a feature for analyzing a blood sample, this means that the analysis feature may or may not be present, and, thus, the description includes structures wherein a device possesses the analysis feature and structures wherein the analysis feature is not present.

25       The present invention provides new and novel devices, methods and systems for the repair of a valve and for their modification and subsequent improvement in valve function. More specifically, in some embodiments, the present invention achieves these repairs using percutaneous endovascular techniques that minimize trauma to the patient and provide reduced recovery time and cost. One particularly useful and immediate  
30       benefit for these devices, methods and systems is in the bringing together, or coaptation, of heart valve leaflets so that they close properly against the relatively high pressures during the contraction of the heart muscle so as to improve the pumping efficiency of the heart muscle.

In the various embodiments, the devices, methods and systems of the present invention provide connection and/or reconnection of body tissues, whether disconnected by trauma, surgery, disease, normal anatomy, or other means., although the devices described herein may, in fact, be used during open-heart surgery or minimally invasive heart surgery. By way of illustration, and without limitation, the devices, methods and systems are useful for the repair of the atrioventricular valves of the heart, particularly the mitral valve. In one embodiment, it may be desirable to perform the repair endovascularly, advancing the devices and systems through the major blood vessels leading to and exiting from the heart, and using these conduits as natural pathways for the devices to access the valves of the heart. Although the repair of the mitral valve will be discussed in detail, it can be appreciated that the devices, methods and systems described herein can easily be adapted to repair, connect, or bring other various body tissues into closer proximity to one another. At least some of these objectives will be met by the novel inventions, devices, methods and systems described hereinbelow. Those skilled in the art will immediately recognize that various combinations, modifications, and equivalents of the inventions described herein can be used without departing from the scope of these inventions.

Referring now to Figure 1, in one embodiment of the present invention, a tissue connection device 10 suitable for minimally invasive delivery comprises a first support ring or annular support ring 12 and a second support ring or attached clamp 14 that secures the ring 12 to the opposite sides of the valve tissue. The first support ring 12 provides support for the annular ring of tissue surrounding the heart valve or other target site so that proper coaptation may occur with the valve leaflets (see Figure 5). As seen in the embodiment of Figure 1, the first support ring 12 may be substantially in a first plane while the second support ring 14 may be substantially in a second plane roughly parallel to the first plane.

Referring now to Figure 2, delivery of the device 10 may be accomplished by straightening the first support ring 12 and second support ring or clamp 14 and inserting device 10 through an elongate delivery device 20 such as, but not limited to, a guide catheter that may be used to access the chambers of the heart. As seen in Figure 2, the device 10 is an elongate member that assumes a substantially linear configuration when placed inside an appropriately sized guide catheter. In one embodiment, the guide catheter may be sized between about 3 and 15 French (1mm to 5mm diameter). When the

device 10 is removed from the delivery device 20, the tissue connection device 10 may assume a coiled configuration as shown in Figure 1.

Referring now to Figure 3, the delivery device 20 such as a guide catheter may be inserted at a location remote from the heart such as the femoral artery, brachial artery,  
5 inferior vena cava, jugular vein, etc. In this example, delivery device 20 is then advanced through the vessel to the heart and across the target valve. As the device 10 in a straightened ring or linear configuration is advanced out the distal end of the catheter, the device 10 begins to regain its pre-formed coil or circular shape.

Referring now to Figure 4, following deployment of the first support ring 12, the  
10 delivery device 20 is pulled back to the proximal side of the valve where the clamp portion or second support ring 14 of the device 10 is deployed.

As seen in Figure 5, the tissue connection device 10 when deployed in the heart valve captures a tissue T between the first support ring 12 and the second support ring 14. The clamping action of device 10 reduces the dilation of the valve formed by tissue T,  
15 thus urging the leaflets closer to the center of the valve. It should be understood that, in some embodiments, configuration may be reversed where the second support ring 14 is on the bottom of the valve and the first support ring 12 is located on top. Furthermore, as seen in Figures 1-5, the first support ring 12 may be thicker or have a greater radial thickness than the radial thickness of the second support ring 14. The greater radial  
20 thickness may provide improved support or capture to tissue engaged between the rings. Additionally, the second support ring 14 having a smaller radial thickness may be more easily situated on sides of the valve with chordae or other materials that may interfere with proper device seating. Still further, as discussed for Figures 7A and 7B, the varying thicknesses may also provide a desired reshaping of tissue captured between the rings 12  
25 and 14 to reduce dilation of the valve tissue.

Referring now to Figure 6, in another embodiment of the present invention, the device 10 may be configured for use with a straightening mandrel 30 that is used as a delivery device 20 to deploy the device 10 to the target site. As seen in Figure 6, the straightening mandrel 30 may pass through a lumen 32 in the first support ring 12 and a  
30 guide loop on the second support ring 14. Thus in this embodiment, the tissue connection device is constrained through internal straightening parts instead of externally constraining parts when a guide catheter is used. The device 10 is loaded onto a straightening mandrel 30 or guide wire for delivery and upon removal of the mandrel or

guide wire, the annuloplasty ring and/or clamp reverts back to its pre-determined remembered shape, typically in its valve supportive configuration. The hollow device 10 and its removable straightening guide wire/mandrel are also adaptable for use with each of the other designs described within this specification, and is not limited to just the annuloplasty ring and clamp configurations.

Referring now to Figures 7A and 7B, another embodiment of the present invention will now be described. For ease of illustration, the rings are shown to be touching. It should be understood that tissue may be engaged between the rings and captured therebetween. In the embodiment of Figure 7A, the first support ring 12 has a larger circumference than the second support ring 14. The ring 14 engages an inner circumferential surface 40 of the first support ring 12. This provides a radially inward force as indicated by arrows 42 on a tissue captured between the rings. The outer ring, in this case first support ring 12, may engage the tissue first and then the second ring 14 will engage the tissue and pull it inward. For heart valve reshaping, this will bring the valve leaflets closer to the center and reduce dilation of the valve minimize leakage and regurgitation.

Figure 7B shows another embodiment where the ring 44 has substantially the same diameter or circumference as the first support ring 12. The ring 44, however, has a cross-sectional geometry wherein the ring 44 only engages the inner circumferential surface 40 of the first support ring 12. Again, the rings will draw tissue radially inward as indicated by arrows 42.

Referring now to Figures 8A and 8B, the connection between the support ring 12 and the clamping ring 14 may have variations depending on the valve anatomy, location, and disease condition. For instance in one embodiment, it may be desired to have the connection between the two structures in the center of the valve such that there is no interference with the movement of the valve leaflets (Figures 8A and 8B). A portion 50 of the tissue connection device will be configured to extend through the center of the valves.

Referring now to Figure 9, an alternative embodiment of the present invention has a portion 52 of the elongate member that transverses through the leaflet tissue towards its most outer edge where there would be little or no interference with the valve leaflet. Additionally, this position for the connection would allow the entire device to remain out of the flow of blood through the valve opening. This would have the advantage of no

disruption of blood flow through the valve and minimizes bloodstream turbulence and the potential formation and/or dislocation of blood clots around the device.

Referring now to Figures 10A through 10C, to aid in the proper seating or apposition of the valve annular support structure against the valve tissue, detachable threads or sutures may be attached at various points around the device. As seen in Figure 10A following deployment of the distal structure, whether first support ring 12 or second support 14, the threads or sutures 60 may be pulled proximally towards the guide catheter, thereby properly seating the structure to the underside of the valve. At least one thread or suture 60 would aid in proper seating, preferably three, so that the orientation of the structure could be adjusted against the valve. The location of each thread or suture 60 on the structure may be identified with unique radiopaque markers 62 to help in the choice of which part of the structure and which corresponding thread needs additional tension for optimum valve support. After positioning the device 10 but before permanent deployment, the improvement in valve function may be assessed. Valve function may be assessed by any suitable means such as angiography, magnetic resonance imaging, ultrasound imaging, trans-esophageal echocardiography and the like. Following verification of improved valve function, one end of the releasable thread could be pulled, removing the thread from its connection to the valve support structure. (See Figure 37 for removal of thread.)

Materials used in the construction of the annular support ring 12 or the second support ring/clamping device 14 include, but are not limited to, Nitinol, superelastic metallic alloys and plastics, PTFE, silicone, stainless steel, ceramics and/or other suitable materials or combinations thereof. Additionally, shape-memory alloys and plastics may be used for the support structure and/or the clamping structure in order for the device to be delivered in a straightened condition and, when heated to a temperature above its transition temperature, the valve support structure and/or the clamping structure assume their predetermined geometries. In one embodiment, the temperature of the body would be sufficient to transform the shape of the shape-memory material into its ring and clamp configuration. In another embodiment, energy is applied to the device using electrical, radio frequency, microwave, heated solutions passed through the guide catheter, or other suitable energy source to transform the shape-memory material to its remembered clamping and support shape. Still further, the exterior surface of the first support ring 12 or second support ring 14 may be conditioned to accept penetration or engagement with a

needle carrying a suture. As seen in Figure 10A, the surface may have a mesh or other covering 64 to facilitate coupling with sutures 60. The mesh may be made of a variety of materials such as Dacron® or other suitable material. For ease of illustration, only a portion of the ring 12 is shown to be covered with mesh, though it should be understood that the entire ring may be covered with mesh. Other methods may also be used to facilitate such eyelets, apertures 66, anchoring locations, or connection devices on the ring 12. The ring 12 may also be made entirely of a penetrable material so that sutures may be easily placed in the device. The ring material may also be made porous in order to promote endothelialization of the ring around the valve. A more secure device may aid in the support the implantable ring provides to the valve tissues. Suitable materials for the ring include Nitinol, ceramics, and plastic polymers. Additionally the materials used may elude drugs that may assist in the promotion of endothelialization. Alternatively, the ring may be surrounded by materials such as polyester that promotes tissue ingrowth and endothelialization of the device.

Referring now to Figure 10B, in another embodiment of the device 10, sutures 60 may be secured to both the first support ring 12 and the second support ring 14 such that, when in its desired position, the sutures apply additional force to the rings 12 and 14 in order to increase the clamping force between the two structures and provide additional support to the valve's annular ring. When delivered, the first support ring 12 and second support ring 14 are spaced apart by a distance 70, wherein a first ring tissue engaging surface 72 is separated from a second ring tissue engaging surface 74.

To secure the clamp section 14 and the support section 12 together, a knot and/or a clamp (or alternate securing means) for each suture 60 is advanced from outside the body, through a guide catheter, and to the device using any one of several knot-tying techniques and/or tools commonly used in vessel closure devices. Additionally, a portion of the suture material 60 may be elastic in order to provide a constant force to the support structure so that during the normal contractions of the heart, the device 10 is allowed limited movement relative to the valve. As seen in Figure 10C, the device 10 when sutured together may engage tissue captured between surfaces 72 and 74 to reform the valve tissue as desired.

Referring now to Figure 11, the device 10 as delivered through a guide catheter 20 with sutures attached, would look similar to the referenced illustration. Each of the pre-threaded sutures 60 attached to the ring structure 12 line up with the corresponding points

on the clamp 14 that are located immediately adjacent to the ring attachment points when in its delivered configuration. This facilitates placement and clamping of the device 10.

Referring now to Figure 12, the standard ring-shaped coil device 10 described is only one configuration that may be delivered in a straight configuration and provide support for the valve or target tissue when delivered to its destination. Other shapes may provide additional support for one or more leaflets of the valve or may provide additional support to a damaged portion of the heart valve annulus. For example in Figure 13A, inner extensions 80 on the ring may provide a backboard for the leaflets preventing prolapse of the valve leaflet during systole of the heart. In another embodiment as seen in Figure 14B, the ring 12 may be shaped more like a bi-lobed leaf for the mitral valve, or a shamrock or cloverleaf configuration 82 for the three-leaflet tricuspid valve of the heart. The additional inner structure(s) of the cloverleaf configuration 82 provides the valve leaflet with an area that it cannot physically go beyond, ensuring proper coaptation of it and its counterpart leaflet against its corresponding stop on the opposite side of the valve.

Referring now to Figure 14A through 14D, a still further embodiment of the present invention will be described. As seen in Figure 14A, sutures 60 may be secured to the tissues surrounding the heart valve at anchoring sites 88. The sutures may be secured in a variety of different methods including but not limited to passing sutures through the heart valve material to be looped through or knotted off using a knot pusher. The sutures may also be connected using anchoring devices as described in commonly assigned, copending U.S. Provisional Patent Application Ser. No. 60/388,250 (Attorney Docket No. 39308-0002) filed June 12, 2002.

As seen in Figure 14B, the sutures 60 may then act as guides to advance a slideable tissue supporting member 90 over the sutures to the tissues surrounding the heart valve. In one instance, the supporting member may be of similar size and shape to a conventional annuloplasty ring typically used to repair heart valves during open heart surgery. In one embodiment, the sutures 60 may be of sufficient length to extend from the attachment locations in the valve tissue to outside the body to allow for attachment to device 90. The device 90 may then be slidably advanced over the sutures to the target tissue. This advantageously allows for precise anchoring of the device 90 at the target site. As seen in Figure 14C, the device 90 may be have a single ring configuration that may be straightened or folded (in other embodiments) to be advanced through a guide catheter to the target site. Alternatively, the device 90 may be a continuous ring without a

break, but foldable to be advanced through the guide catheter. As seen in Figure 14D, a coil ring configuration device 92 may also be used, wherein both coils or rings of the device remain on the same side of the valve tissue. This may allow for additional attachment points on the device 92 or if the coils have varying diameters, different  
5 reshaping options based on different angles of the sutures to provide pulling or securing forces in different directions.

In the invention described, the ring may be advanced over the anchored sutures and advanced to the valve through a typical guide catheter. In such a manner, the entire procedure may be performed percutaneously, resulting in less trauma to the patient and  
10 providing improved valve function without the need for open heart surgery. After the ring is in position on the valve tissues, each of the locations where the sutures pass through the ring are fastened to the ring using the techniques previously described with clamps and/or knots. Alternatively, it may be possible to secure all of the sutures with a single clamp securing each of the sutures together, as shown in Figure , below.

Referring now to Figures 15A and 15B, in another embodiment of this invention, the device 110 consists of two separate halves or clamp portions 112 and 114, each of which may provide support for the valve while maintaining a clamping force between them. Clamp portion 112 may have an annular support 113 or leaflet that supports the tissue. Clamp portion 114 may similarly have an annular support 115 or leaflet that  
20 supports the tissue. The two clamp portions 112 and 114 are connected to each other via a central adjustable fitting. In one embodiment, the central fitting consists of a barbed connector or spine 116 on one device part that mates to a matching insert 117 on the opposite part with a lumen 118.

As seen in Figure 16, the center spine 116 could be split, having a slot 119, to  
25 permit the outer diameter of the spine to be adjustable, allowing the distance between the two parts to be adjusted by the physician *in-vivo*, until the improved function of the heart valve has been observed.

In a further preferred embodiment seen in Figure 17, the distal end 120 of the center spine 116 may incorporate holes 122 on each half of the barbs. Through the holes  
30 122 is a releasable suture or thread 60 that, when tension is applied, compresses the two halves of the spine 116 together, effectively decreasing its overall outer diameter. This permits the upper half of the device to be adjusted prior to release to allow for more distance between the two halves of the device and less clamping force on the valve area.



The complete assembly, including the releasable suture, is illustrated in Figure 18 (for illustrative purposes, the ring and clamp are shown as simple circular structures). In this manner, the clamping force on the valve and annular support device is entirely controlled by the physician prior to its release in the heart.

5           In a further embodiment of the present invention as seen in Figure 19, the device 110 comprises a lumen 130 through the center spine 116. The lumen 130 provides a space through which a slideable and removable guide wire may be inserted for placement of the device. A matching lumen on the mating half 118 of the device ensures that both pieces remain in the same axis when being delivered. Since both parts of the connector  
10           are maintained in axial alignment, securing the devices together is accomplished by pushing the two devices together.

          A pushing device 134 of Figure 20, consisting of a tubular member, allows for tension to be placed on the releasable suture 60 without disrupting the location of the valve support device by holding the center spine in position while tension is applied to the  
15           suture. After the desired improvement in valve function has been obtained, the suture is removed by simply releasing one end of the suture and pulling on the other end until the entire suture has been removed from the body. Additionally, other release mechanisms include clamping jaws, screw threads, and other mechanical means, that are releasably connected to the support structure in order to maintain control over the device and to  
20           remove the structure from the body if improvement is not realized or for any other reason.

          Again, each of the halves 112 and 114 of the device may be hollow allowing for them to be straightened over a mandrel or guide wire for delivery into the valve area. Upon delivery to the valve area, the device(s) are advanced off the removable mandrel/guide wire and they revert back to their pre-determined shape.

25           In addition to the various coil type annular support rings described above, other types of annuloplasty device may also be used in accordance to the present invention.

          Referring now to Figures 21 and 22, in another embodiment of the present invention, a valve support structure 210 is delivered to the valve area via a guide catheter. The device 210 comprises of a central body 212, a first leaflet clamp 214 defining an  
30           upper compressive portion, and a second leaflet clamp 216 defining a lower compressive portion. The clamp 212 and clamp 214 may be positioned to engage the valve leaflet therebetween.

Referring now to Figure 23, the number of leaflet clamp sets on the device may match the number of leaflets of the valve. For instance, the mitral valve device of this invention may have two sets of clamps. The tricuspid device design may, but is not required to have, three sets of leaflet clamps 220 as seen in Figure 23. In either instance, the clamps are connected at a central location and radiate outwards towards the valve leaflets.

Each leaflet clamp 220 may have a different geometry, depending on the condition of the valve. For instance, if more support is desired at the outer edge of the leaflet, the clamp could have a larger diameter in that area. Figure 24 shows a wire loop leaflet clamp 220 having a curved configuration where the wire extends radially outward and then returns to the central body 212. Figure 25 shows an embodiment where the change in width is more pronounced as the wire loop reaches the outer radial portion of the clamp. Figure 26 shows an embodiment having an oar or paddle configuration. It should be understood that a variety of different geometries may be used to support the leaflet clamps.

Referring now to Figures 27A-27C, the cross section of the clamp 220 may also have various geometries. For instance, it may be desirable to distribute the clamping force over a larger area, in which case a flattened cross section would be appropriate as seen in Figure 27B. Alternatively, rounded cross sections may be used in areas where there may need to be increased force on the tissue surface as seen in Figure 27C.

It can be appreciated that there may be any number of configurations for the clamps 214 and 216. For instance, if most of the support for the valve is needed at the area of the annular ring, the clamps may not provide any clamping force on the leaflets themselves, but would be of sufficient overall diameter and distance away from the central hub so as to provide support in the annular area of the valve. Conversely, if a percutaneous procedure yielding similar results to the "bow-tie" procedure is desired, the clamps may be of relatively small outer diameter. In this manner, only the leaflets would be clamped together more central to the device, effectively decreasing the movement of the leaflets, and providing a forced coaptation. Additionally, as seen in Figure 27D, a combination of both annular support 222 and leaflet coaptation 224 could be achieved in the same device by providing multiple clamps of different diameters to support both the valve leaflets and the valve's annulus.

Referring now to Figures 28-30, delivery of the device 210 may be achieved through a guide catheter 230. Each of the leaflet clamps 214 and 216 may be made of a superelastic material such as, but not limited to, Nitinol, such that the leaflet clamps 214 and 216 can be folded up into the guide catheter to assume a folded configuration. As  
5 seen in Figure 28, the leaflets clamps are deflected towards a longitudinal axis 231 of the central body to provide a reduced diameter 232 so that the device 210 will fit inside the guide catheter but still assume an expanded configuration with an extended diameter upon exiting the catheter.

As seen in Figures 29 and 30, upon release across the heart valve V, the leaflet  
10 clamps 214 and 216 return to their functioning state with the extended diameter 234. Alternatively, the device 210 may be made of any one of a number of shape memory alloys, allowing it to be delivered in a straight configuration through the guide catheter, and re-assuming its functioning form following the application of energy in the form of electrical, radio frequency, microwave, and such. In any case, the guide catheter is  
15 traversed across the target valve. At the desired location, the device is pushed out the distal end of the guide catheter and upon exiting the guide catheter as seen in Figure 29, the distal leaflet clamp 214 assumes its clamping dimensions.

The guide catheter 230, still with the proximal leaflet clamps 216 inside in their folded configuration, is then retracted proximally across the valve opening where the  
20 remainder of the device 210 is delivered. The leaflet clamp 216 then extends to their preformed configuration with diameter 234, engaging or urging the valve leaflet against the opposing clamp 214 as seen in Figure 30.

Referring now to Figures 31-35, there are several ways the mitral valve can be accessed percutaneously to deliver the devices described herein, although it should be  
25 understood that the devices may be used during open heart surgery as well. As seen in Figure 31, one route utilizes the femoral artery approach where the guide catheter 250 is threaded through the femoral artery in the groin and advanced retrograde against the flow of blood, over the aortic arch, through the aortic valve, into the left ventricle of the heart, and directed towards the mitral valve.

Referring now to Figure 32, a second approach that may be used during  
30 percutaneous valvuloplasty procedures involves the venous approach to the heart. The guide catheter 252 is advanced through the vena cava into the right atrium of the heart and is directed across the atrial septum of the heart into the left atrium of the heart. This

approach has been demonstrated to be well-tolerated by the body with few adverse events.

Referring now to Figure 33, a further method for device placement is described herein that provides unique advantages for devices attempting to modify the performance of the mitral valve percutaneously. First, a trans-septal guide catheter is advanced through the atrial septum of the heart to the superior side of the mitral valve. An extra long guide wire 254, is then advanced through the guide catheter 252 and into the left ventricle. A second guide catheter 250 is advanced to the left ventricle of the heart via the arterial approach. A snare (not shown) may then be advanced through the arterial guide catheter 250 and captures the distal end of the trans-septal guide wire 254. The snare is retracted through the arterial guide catheter 250 where the distal end of the guide wire is captured and secured outside the body. In effect as shown in Figure 34, the guide wire 254 provides a passage from either or both directions, arterial or venous, to the mitral valve of the heart.

Referring now to Figure 35, a support ring 114 when threaded over the guide wire from the arterial side need not even cross the mitral valve to provide support to the ventricular side of the valve. Similarly, a second support ring 112 forming device 110 when combined with ring 114, intended to provide support to the atrial side of the mitral valve also need not cross the valve when delivered via the trans-septal route. In this manner, the two halves of mitral valve device 110 can be delivered through the two guide catheters and meet up at the mitral valve. The guide wire 254 additionally ensures that the two mating parts of the device remain in axial alignment when assembled across the valve.

Referring now to Figure 36, the device 10 or any of the other devices 110 or 210 as described herein, may be included in a kit 300 contained in a pouch or container 302. Instructions for use IFU are also contained in or attached to the container 302. The instructions provide a method for using device 10, a method for attaching device 10 to tissue, or instructions on how to deliver device 10 or similar device using a delivery device 20 such as a catheter or straightening mandrel that may also be contained in container 302. It should be understood that the kit 300 may include anchors and delivery devices 500 in addition to or in place of devices 110 and 210.

Figure 37 shows that sutures or threads may be removed from the angioplasty ring.

Referring now to Figures 38 and 39, it can be appreciated that the cross section of the guide wire 310 may be shaped to ensure the proper orientation of the two device halves. In this manner, torqueing of the guide wire 310 with the device 312 slideably attached also orients the device 312 loaded on the guide wire. The steerability of the guide wire 310 and the valve device may help in the proper orientation of the clamps 314 of the device onto the leaflets of the valve.

Referring now to Figure 40, additionally in a still further embodiment, an integral bump 320 on the guide wire 322 may aid in providing additional force to connect the valve support device or to seat it against the tissues of the heart valve. The bump 320 on the guide wire 322 provides enough interference with the device so that as the guide wire is advanced or retracted, it pulls the device along with it.

Referring now to Figure 41, additional placement techniques for the device according to the present invention include using thoroscopic techniques to place the devices. During this procedure, a small port(s) is usually used to access the heart tissues. The port is typically paced between the ribs using laparoscopic methods. A metallic tube or guide catheter is then advanced up to the heart tissues to gain access to the major vessels and the exterior of the heart muscle. The technique that may be particularly useful is where the anchor is inserted through the heart muscle at or near the level of the damaged valve.

The hypo delivery tube 330 pierces through the heart muscle into the atrium or the ventricle near the valve. The needle is then further advanced across the interior of the heart to the opposite side of the valve where it again pierces through the heart wall. The anchor 332 is then deposited on or in the opposite side of the heart and the suture 334 left behind in the path of the needle as the hypo is retracted from the heart muscle as seen in Figure 42.

A clamp 336 may then be advanced down the suture to the initial side of the piercing. As the clamp 336 is further advanced, the sides of the heart are drawn closer to each other, assisting the valve leaflets in proper coaptation and improved function.

It should be understood that although a suture is described, a steel rod or similar support structure may be used to transverse through the heart muscle. The main concept is that opposite sides of the valve a brought closer to one another by an external force on the heart muscle. Alternatively, if valvular stenosis is being treated, the valve can be

forced open in a similar manner. In this manner, the spanning structure is rigid since it is under compression from the force of the heart muscle on the spanning rod.

Yet another embodiment of the present invention comprises the ventricular half of the annular support device having struts 340 instead of a ring or clip-like structure. The struts 340 are designed to atraumatically navigate through the chordae tendonae in the ventricle of the heart. During advancement through the guide catheter 342, the legs are extended distally. Upon exiting from the guide catheter, the legs 340 begin to spread outwards from the tip of the guide catheter towards the circumference of the valve. During their advancement, the legs gently push aside the chordae, if any, in their pathway.

The ends of the legs or struts 340 may be shaped in any of a number of ways to allow for either more surface area on the ventricular side of the valve or to advance through the chordae easier. For instance as seen in Figure 45, small spherical bulbs 344 on the ends of the legs provide a smooth leading edge for the legs with little risk of snagging a chord as the legs advance through the chordae. After traversing through the chordae, the landing pads on the legs secure themselves on the ventricular side of the mitral valve, either at the leaflet or directly onto the annulus of the valve. In other embodiments, the ends of struts 340 may have a hockey feet 346 configuration or a zig-zag 348 configuration.

Referring now to Figure 46, another aspect of modifying the heart valve for improved function includes devices that treat valvular stenosis. These devices provide expansive forces to the valvular annulus in order to increase the open area of the valve through which blood flows. One such device 350 utilizes an outward expansive force to apply pressure to the annular area of the heart valve as indicated by arrows 352. The coil is delivered through a standard guide catheter and, upon exiting the distal end of the guide catheter, the device assumes a pre-determined generally ring-shaped structure that presses itself against the heart wall, either immediately superior (atrial side) or inferior (ventricular side) of the valve.

Alternatively, the device may be generally cylindrical in shape, and upon exiting the guide catheter, it assumes a larger diameter that presses against the heart wall, either immediately superior (atrial side) or inferior (ventricular side) of the valve. Furthermore, the device may be hollow, allowing for it to be straightened for delivery over a removeable straightening mandrel or guide wire. Upon removal of the mandrel or guide

wire, the ring reverts back to its larger diameter pre-determined shape and provides a force on the interior of the heart wall, thus modifying the function of the heart valve in its vicinity.

Referring now to Figure 47, another aspect of this invention provides devices,  
5 methods and systems for suturing and repairing tissues of the body. Specifically, tissues can be “cinched” together, or brought into closer proximity to one another, using the devices described herein. In one embodiment of this invention, anchors 360 are attached to the tissues to be cinched. Attached to the anchors 360 are sutures 362. A slideable clamp is attached to the sutures. As the clamp 364 is slid closer to the anchor points, the  
10 tissues are brought closer together. When the desired position of the tissues has been achieved, the clamp 364 is set in position and the excess suture material from each anchor point is severed and removed.

The anchors 360 may be of any of a number of configurations. For instance as seen in Figure 48, a spear-like design would enable the anchor to penetrate tissue with the  
15 barb providing adequate resistance to the tension applied to the suture during the cinching process.

Referring now to Figure 49, in the case of repairing a heart valve, two or more anchor 360 may be placed in any of the tissues surrounding the valve leaflets, including the leaflets themselves. Following the proper placement of the anchors and attached  
20 sutures 362, the slideable clamp 364 is advanced over the sutures and adjusted to provide adequate tension on the anchor points on the valve to provide improved coaptation of the valve leaflets. When adequate improvement in the function of the valve has been obtained and verified, the clamp is set in place and the excess suture material cut and removed.

25 For illustrative purposes, the clamp 364 is shown as a tubular member, however, simple means of securing the tension on the sutures may be accomplished by any one of several means. For instance as seen in Figure 50, a simple knot 366 tied in the proximal end of the sutures and advanced towards the valve by a knot pusher, would provide adequate means for securing the tension in the sutures.

30 Referring now to Figure 51, in another embodiment, one or more anchors 360 and sutures 362 are secured to the tissues surrounding the heart valve. The sutures then act as guides to advance a slideable tissue supporting member 370 over the sutures 362 to the tissues surrounding the heart valve. In one instance, the supporting member 370 may be

of similar size and shape to a conventional annuloplasty ring used to repair heart valves during open heart surgery.

In the invention described, the support member 370 may be advanced over the anchored sutures and advanced to the valve through a typical guide catheter. In such a manner, the entire procedure may be performed percutaneously, resulting in less trauma to the patient and providing improved valve function without the need for open heart surgery. After the support member 370 is in position on the valve tissues, each of the locations where the sutures pass through the ring are fastened to the ring using the techniques previously described with clamps and/or knots. Alternatively, it may be possible to secure all of the sutures with a single clamp 372 securing each of the sutures together, as shown in Figure 52.

In one embodiment, the support member material may be made porous in order to promote endothelialization of the member 370 around the valve. A more secure device may aid in the support the implantable ring provides to the valve tissues. Suitable materials for the ring include nitinol, ceramics, and plastic polymers. Additionally the materials used may elude drugs that may assist in the promotion of endothelialization. Alternatively, the support member 370 may be surrounded by materials such as polyester that promotes tissue ingrowth and endothelialization of the device.

Referring now to Figure 53, in another aspect of this invention, the anchors 360 incorporate a loop 376 of material or a lumen through which a suture may slide 380. The first anchor 360 placed typically has a non-slideable suture attached. Once the first anchor point has been secured in the desired location, subsequent anchors 378 are slid over the primary suture and secured to the tissues of the valve.

As tension is applied to the primary suture 380, each of the anchor points are brought into closer proximity to one another (see Figure 57), resulting in improved coaptation of the valve leaflets and improvement in the function of the heart valve. Following the final anchor attachment to the tissues, a single clamp 372 or knot is advanced to the location of the final anchor and secured in place following verification of improved function. Valve function may be verified by any one of many suitable means including, but not limited to, echocardiography, angiography, magnetic resonance imaging, etc.

Referring now to Figure 54, the anchors may be of any suitable design to provide adequate prevention of dislodgement when the primary suture is place in tension. An



alternative embodiment to the barbed spear is a "T" bar design anchor 382 is used in various alternative procedures such as in gastrostomy placement.

Referring now to Figure 54, in one embodiment, the "T" bar 382 is placed via a hypodermic needle or tube 384. The needle 384 punctures through the tissues to be  
5 cinched and then the "T" bar 382 is deposited on the opposite side by a simple mandrel or "T" bar pusher. The needle is then retracted leaving the "T" bar anchor securely fastened to the opposite side of the tissue as seen in Figure 56.

Subsequent anchors are added by removing the "T" bar pusher from the catheter, loading a slideable anchor over the primary suture, and advancing the anchor through the  
10 hypo tube to the next desired position. The target tissue is then pierced by the "T" bar delivery hypo tube, the "T" bar anchor pushed out the end of the hypo, and the hypo retracted, leaving the "T" and primary suture attached to the anchor point. Additional anchors may be placed in a similar fashion as seen in Figure 57.

Referring now to Figure 58, in this manner, multiple anchor points 388 may be  
15 placed around a heart valve or other tissue that is in need of support. As tension is applied to the primary suture, the anchors provide the points at which constriction occurs and the overall diameter of the valve annulus is reduced much like the use of a belt through the belt loops on a typical pair of trousers. By this method, several series of anchors and sutures may be placed that specifically provides constriction on only those  
20 areas of the valve that may be in need of cinching.

It is important to note that although the repair of the heart valve is described, this device and technique may also be very useful in the non-surgical repair of other tissues within the body. For instance, Gastrointestinal Reflux Disease may be treated by using these techniques on the sphincter between the esophagus and the stomach. By effectively  
25 decreasing the overall diameter of the excess opening typical of this disease, normal function may be restored. Additionally, urinary incontinence may be treated using similar techniques and devices on the sphincter between the bladder and the urethra. In these instances and others, surgery may be significantly reduced or eliminated, thus sparing the patient from the risks of surgery and the necessary recovery from such trauma.

Referring now to Figure 59, another technique that can be used is where each of  
30 the anchors 390 are slidable with no primary anchor. Instead of the initial anchor having a permanent suture attached, a single (or multiple strands) suture 392 is threaded through a hoop on each of the anchors 390 with both ends of the suture exiting through the

delivery guide catheter. The tissue is then cinched together by advancing a knot or clamping device 364 using the two ends of the suture as the point where the tension is applied.

Referring now to Figure 60, if a clamp 364 is advanced towards the anchors, the clamp itself may have a means to both clamp the ends of the suture together and simultaneously cut the excess suture material from the site. Figure 60 shows a clamp 400 with a crimping area 402 and a cutting area 404.

Another method is where each of the anchors has non-slidable sutures permanently attached. In this instance, all of the ends of the sutures can be pulled together, and tied or clamped with a single knot or clamping device.

Referring now to Figure 61, the hypodermic delivery tubing 410 for the "T" bar anchors or similar anchors may be of any number of suitable configurations to deliver the anchors. In one embodiment, the tubing 410 employs a simple sharpened needle tip 412 to puncture through the valve, leaflets, and/or the heart tissues surrounding the valve. The application of forward pressure on the tubing provides sufficient force for the tubing 410 to pierce the tissues and deliver the anchor to the opposite side of the heart structure.

Referring now to Figure 62, in another embodiment, the tubing 414 has a sharpened inner removable piercing obturator 416 that punctures through the heart tissues. After the tubing is through the tissues, the obturator is removed, allowing the anchor to be passed through the hypo tubing to the heart tissues.

Referring now to Figure 63, in another embodiment, the obturator tip 418 has self-tapping threads 420 on its distal end. Torqueing of the obturator screws the delivery hypo into the heart tissues. After the hypo 414 has been delivered to the desired location, the obturator is removed, allowing the anchor to be passed through the hypo tubing.

Referring now to Figure 64, in another embodiment, the hypo tube 422 has threads 424 on its surface to permit the engagement of the hypo tube 422 with very little force. Torqueing of the hypo tube 422 screws the tubing into the heart tissues without requiring additional forward force on the tubing. In some cases, it does not require forward force greater than that used with a sharpened hypo tube. Once through the tissue, anchors may be advanced through the hypo 422 to their desired position.

Referring now to Figure 65, another embodiment utilizes self-tapping threads 420 on both the inner cannula 426 and the outer delivery hypo tube 428, preventing the possibility for coring of the tissue with the hypo tubing alone.

Referring now to Figure 66, in yet another embodiment, the anchor 430 itself employs self-tapping threads 420 to engage the tissue and advance itself to the opposite side of the targeted tissue.

5 Referring now to Figure 67, alternatively, the anchor 432 may be a simple self-tapping thread or a helix of sharpened wire similar to the distal tip on an active-fixation pacemaker lead that is secured to the heart tissue by torqueing through the tissue.

Referring now to Figure 68, one possible improvement on the helical anchor 434 is that the helix may be of variable radii. For instance, the initial distal engaging winds of the helix may be of relatively small diameter, increasing in diameter proximally.

10 Referring now to Figure 69, in this instance, additional anchoring force is provided, allowing for a more secure attachment. Additionally, the suture material 440 may be attached to the distal end 442 of the helix such that as more force is applied to the anchor by the suture, the anchor 444 tends to collapse upon itself, further providing additional support to the tissues in which it is attached.

15 Referring now to Figure 70, delivery of the anchor 432 is accomplished by securing the anchor 432 to a releasable delivery shaft 446. In one method of delivery, the anchor 432 is secured to the heart tissue by clockwise motion. Engaging threads 448 on the delivery shaft 446 allows clockwise rotation of the anchor for securement. Counterclockwise rotation of the delivery shaft 446 disengages the anchor 432 from the  
20 threads 448 on the delivery shaft. The delivery shaft is then removed from the guide catheter, leaving the anchor firmly secured within the heart tissue.

Referring now to Figure 72, in another embodiment, the distal end of the guide catheter 450 releasably locks or engages at least a portion of the anchor 432. The anchor 432 is delivered with the engaging portion of the guide catheter retracted, and following  
25 delivery of the anchor, the guide is then advanced up to the anchor point to engage a portion of the anchor. By rotating the delivery shaft 450, the anchor is held in place, while the delivery shaft disengages. The guide catheter is then retracted from the anchor, leaving the anchor secured to the tissue.

Referring now to Figure 72, another method of delivery for the anchors is the  
30 simultaneous deployment of multiple anchors 460 at a time. In this manner, the delivery shafts 462 for two or more anchors are deployed at a variable distance apart. For instance, the ends of the delivery shafts 462 may be pre-shaped into a curved geometry

such that as they exit the guide catheter, they progressively move further apart from each other.

Referring now to Figure 73, the more the delivery shafts 462 are advanced out the guide catheter, the greater the distance between the anchors 460. In this manner, several  
5 anchors 460 can be delivered in a pre-determined configuration at a pre-determined diameter away from the guide catheter. This eliminates the need to individually place each anchor at a desired location. Each projection outward from the guide catheter tip need not contain an anchor. In other words, one or more additional projections 464 may  
10 be used to center the device within the lumen of an artery or within the valvular tissue such that the anchors being delivered are oriented in the desired directions.

The anchor(s) may be porous in order to promote the endothelialization or encapsulation of the anchor in the tissue to obtain a more secure, long-term hold in the valve tissue. Suitable materials include ceramics, nitinol, elgiloy, stainless steel and the like. Alternatively, various polymers may be used that may or may not elude drugs to  
15 further promote endothelialization of the heart tissues into and around the anchors and/or the various other devices and inventions described herein. Additionally, the device may be used to close tubular organs, punctures or vessels from inside the tissues. In one instance, the fallopian tubes of a woman may be closed for permanent birth control. The device is threaded through a fallopian tube access catheter trans-cervically to the interior  
20 of the fallopian tube. One or more anchors may be delivered through the wall of the fallopian tube from the inside. The anchors are then secured to the exterior of the tubal wall and cinched together to close the tube. A clamp or knot that provides closure force is advanced to the site and secures the individual suture leads together. Again, the sutures may be fibered, stranded or bundled in order to facilitate tissue ingrowth and a more  
25 permanent occlusion of the fallopian tube. In this same fashion other organs, tissues and body passageways may be closed from the inside in order to effect the desired therapy or treatment.

Referring now to Figure 74, another aspect to the delivery of the anchors is in providing a means for the guide catheter to grip or hold the tissues in close proximity to  
30 the distal end of the guide catheter. One such means is the provision for a simple vacuum to be placed on the proximal end of the lumen of the guide catheter 470. As the tip of the guide comes close to a soft tissue, the tissues are sucked closer to the guide catheter tip and held in place by the suction.

This vacuum device, the guide catheter 470 with an attached or detachable vacuum source, may also be particularly useful in the fixation of the stomach wall prior to percutaneous gastrostomy placement.

Referring now to Figure 75, it is important to note that the anchors 460 may  
5 provide a means to improve the function of the heart valve alone, they may also be used to provide an anchoring means for various other devices used in the interventional treatment of cardiovascular diseases. For instance, although providing a means to secure the percutaneous annuloplasty rings described earlier, they may also be used to secure or affix a stent 480, or stent-graft to a vessel wall. In this application, first the anchors are  
10 delivered and secured to the desired tissue, such as the abdominal aortic vessel wall. The sutures on the anchors are threaded through loops such that the stent device can slide over the sutures. The stent is then advanced to the anchoring site. Knots or clamps are then advanced up to the stent so that the stent is then secured to the vessel wall at each of the anchor points.

15 Alternatively, the anchors may be added after the stent has been delivered. The stent has specific points of attachment through which the anchors are delivered into the vessel wall. In this manner, the need for any suture material is completely avoided as seen in Figure 76.

Referring now to Figure 77, another aspect of this invention is an artificial valve  
20 490 to replace a destroyed natural valve within the body. The natural valve may be one of the heart such as the mitral or aortic valves. Alternatively, the valve may be used in the legs of a patient with venous insufficiency. By providing improved fluid dynamics over the patient's natural valve(s), pooling of blood in the legs, typical in this disease, is minimized. The valve device 490 includes the valve itself, as well as an outer expandable  
25 support structure that secures the valve within a desired segment of blood vessel. The valve 490 may be made from materials typical of cardiac valves, such as carbon, silicone, nitinol and the like. Alternatively, the valve of this invention may be a tissue valve from a donor host, similar to porcine or bovine valves used for cardiac valve replacement. The valve may be processed venous valves from these animals, or they may be made from a  
30 valve structure that is temporarily grown within the living tissues of a host animal.

Yet another aspect of this invention provides a means for repairing the chordae tendonae that connect the leaflets of the mitral valve to the ventricular wall. In this device, the anchor is directed through the leaflet of the valve from the atrial side of the

heart and placed within the ventricular wall. The leaflet is held in place by a knot or a clamp secured to the atrial side of the leaflet onto the suture attached to the anchor..

Several sutures may be place in each of the leaflets in order to prevent prolapse during systole of the heart.

5           Referring now to Figure 78, a still further embodiment of a tube 500 for engagement of the tube 500 into tissue with reduced forward force. Torqueing of the tube 500 screws the tubing into the tissues through the cutting action of the helically cut distal portion 502 of the tube 500. Although not limited to the following, the cutting distal portion 502 may be formed by laser cutting or otherwise cutting a tube to remove material  
10           and form the structure shown. Other patterns may also be cut in the tube so long as they permit the tube to be advanced into tissue via torquing of the tube 500. Once through the tissue, anchors 504 may be advanced through the tube 500 to their desired position. In some embodiments, a pusher 506 may be used. In some embodiments, the anchor 504 may have a diameter substantially similar to that of the inner diameter of the tube 500 but  
15           allowing for unimpeded delivery of the anchor through the tube. A suture 506 may be coupled to the anchor 504.

          Referring now to Figure 79, one embodiment of the tube 500 or elongate delivery device is shown penetrating through tissue T and delivering the anchor 504. Arrow 510 indicates that rotation of the delivery device 500 will cause the distal end 502 of the  
20           device 500 to engage tissue and draw the entire device 500 into and through the tissue. In some embodiments, anchor 504 may have a sharpened tip as indicated by dotted line 512 to allow the anchor 504 to be driven through the tissue.

          Referring now to Figure 80, in this embodiment, a guide catheter 520 may be used to guide the elongate delivery device 500 into the correct location for penetration into  
25           tissue T. It should be understood that the tube or device 500 may have any of the distal tips disclosed herein and may be used with any combination of anchors disclosed herein. The tube 500 may be rotated within the guide catheter 520 to enable the front end of the tube 500 to engage tissue. In other embodiments, the tube 500 is simply pushed forward to pierce the tissue T.

30           Referring now to Figures 81 and 82, the support member 530 after being delivered to a target site, may use a suture 532 to tighten the tissue coupled to the support member 530. The member 530 may be secured by anchors or sutures as described in regards to Figures 14A-14C and Figure 51.

Referring now to Figures 83 and 84, the anchors 504 may be delivered through tissue using a delivery device 500 or the like to send an anchor 504 through tissue T. This technique may be useful in patent foramen ovale (PFO) closure in heart tissue. As seen, a suture 540 with anchors 504 may be used for tissue connection.

5 Referring now to Figures 85 and 86, a still further embodiment of an anchor 550 is shown. The anchor 550 has outward extending member 552 or barbs which will secure the anchor in tissue after delivery from the catheter 500. This may be useful in situations where the anchor 550 does not fully penetrate through tissue and may rely on the barbs for anchoring force.

10 While the invention has been described and illustrated with reference to certain particular embodiments thereof, those skilled in the art will appreciate that various adaptations, changes, modifications, substitutions, deletions, or additions of procedures and protocols may be made without departing from the spirit and scope of the invention. For example, the geometric configuration of the loops of device 10 or 210 may be varied  
15 as desired to provide leaflet support, including shapes such as square, triangular, bowed, rounded, or other configuration. The wire loop elements may also be replaced by solid elements, such as a solid, oar shaped clamp instead of a wire loop. Although device 10 is generally shown to have a circular relaxed configuration, it should also be understood that, in all embodiments, the device may have a square, rectangular, triangular, polygonal,  
20 or other shape that will provide suitable reduction of valve regurgitation. Additionally, bringing together tissues in closer proximity to one another is one method for closing wounds such as catheter puncture sites during percutaneous procedures (angioplasty, stenting, endograft procedures and the like), as well as in stomach stapling for the morbidly obese, gastrostomy placement, etc. These procedures all may benefit from the  
25 inventions described herein. Additionally, any of the inventions and devices described in this application may be manufactured, at least in part, using animal, human or cultured cells and tissues incorporated in whole or in part. These tissues may be harvested or cultured through tissue engineering or altered by the manipulation of their genetic content. In such a manner, these devices may be incorporated into the target location easier, may  
30 be less prone to rejection by the body, or may elude certain chemicals and/or enzymes that may be beneficial to the targeted tissues or the body as a whole.

Expected variations or differences in the results are contemplated in accordance with the objects and practices of the present invention. It is intended, therefore, that the

invention be defined by the scope of the claims which follow and that such claims be interpreted as broadly as is reasonable.



WHAT IS CLAIMED IS:

- 1                   1.       A tissue connecting device, the device comprising:  
2                   an elongate delivery device having a lumen, a proximal end, and a distal  
3                   end;  
4                   wherein said distal end is configured to engage tissue and advance said  
5                   device into tissue;  
6                   at least one anchor deliverable through a lumen of said elongate delivery  
7                   device.
- 1                   2.       The device of claim 1 wherein said delivery device pierces tissue  
2                   through rotation of the delivery device about a longitudinal axis;.
- 1                   3.       The device of claim 1 further an elongate member deliverable to  
2                   the target site via a guide catheter, said elongate member assuming a first substantially  
3                   linear configuration while engaged with said guide catheter and a second substantially  
4                   circular configuration defining a first support ring and a second support ring when  
5                   removed from the guide catheter.
- 1                   4.       The device of claim 2 wherein said elongate member is slidable  
2                   delivered along at least one suture coupled to said anchor.
- 1                   5.       The device of claim 1 wherein a helical configuration is laser cut at  
2                   the distal end of the delivery device.
- 1                   6.       The device of claim 1 wherein threads are formed on the distal end  
2                   of the delivery device and adapted to engage tissue.
- 1                   7.       The device of claim 1 wherein said at least one anchor has threads  
2                   and are adapted to engage tissue.
- 1                   8.       The device of claim 1 wherein said at least one anchor has a helical  
2                   configuration.
- 1                   9.       The device of claim 1 wherein said at least one anchor has a suture  
2                   coupled to a distal end of the anchor.

1                   10.     The device of claim 1 further comprising a plurality of anchors  
2     wherein each anchor is coupled together by a suture.

1                   11.     The device of claim 1 further comprising a plurality of anchors  
2     wherein each anchor is coupled together by a suture.

1                   12.     The device of claim 1 wherein said anchor has a shape selected  
2     from one of the following: screw, a helix, a helix with variable radii, a bar, a hollow  
3     elongate portion or coiled shape.

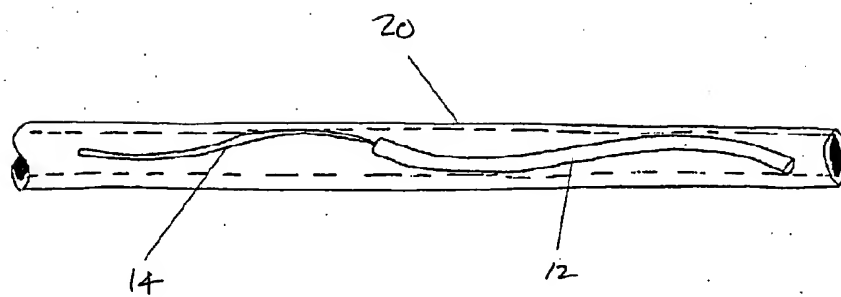
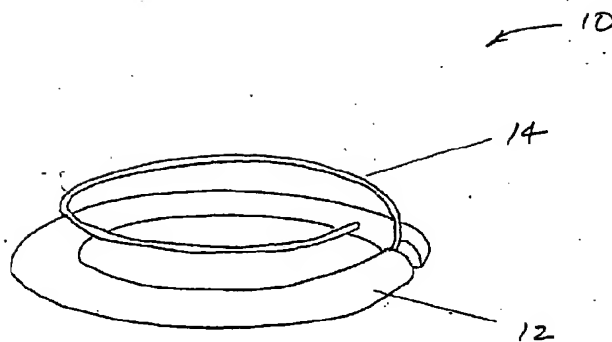
1                   13.     The device of claim 1 wherein said anchor includes an eyelet for an  
2     anchor.

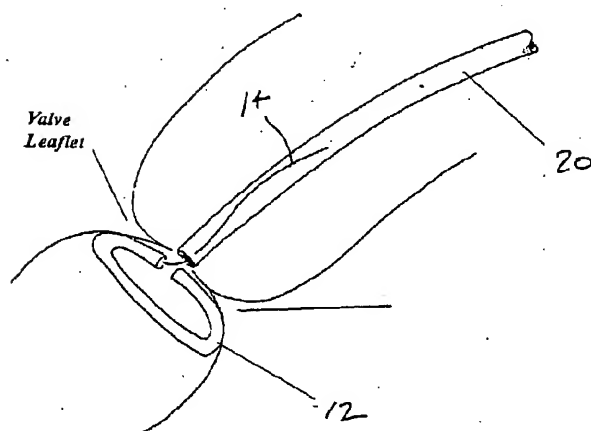
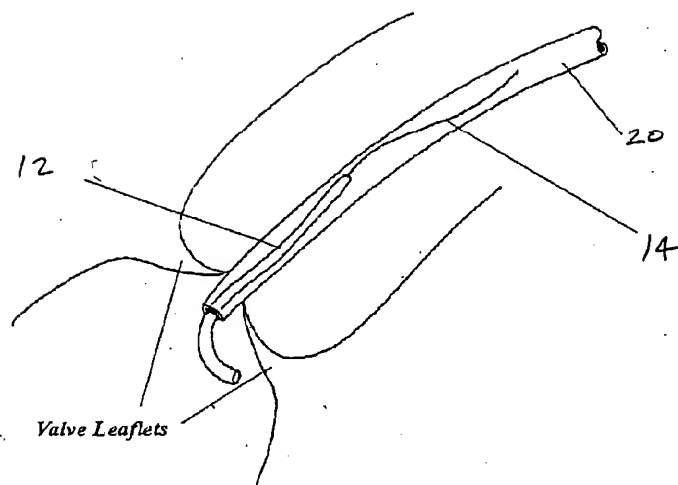
1                   14.     The device of claim 1 wherein said anchor includes means for  
2     attaching into tissue.

1                   15.     A system for tissue connection comprising:  
2                   an elongate delivery device having a lumen, a proximal end, and a distal  
3     end;  
4                   wherein said distal end is configured to engage tissue and advance said  
5     device into tissue through rotation of the delivery device about a longitudinal axis;  
6                   means for anchoring tissue deliverable through said delivery device;  
7                   an elongate member deliverable to the target site via a guide catheter, said  
8     elongate member assuming a first substantially linear configuration while engaged with  
9     said guide catheter and a second substantially circular configuration defining a first  
10    support ring and a second support ring when removed from the guide catheter.

1                   16.     A system for tissue connection comprising:  
2                   a plurality of tissue anchors coupled to a single suture, wherein said suture  
3     is slidably coupled to each anchor, wherein the anchors are configured so that tissue  
4     coupled to each of said anchors will be draw together when the suture is tightened.

1





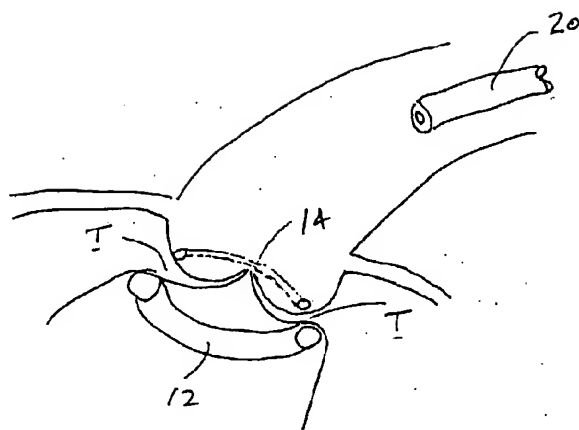


FIG-5

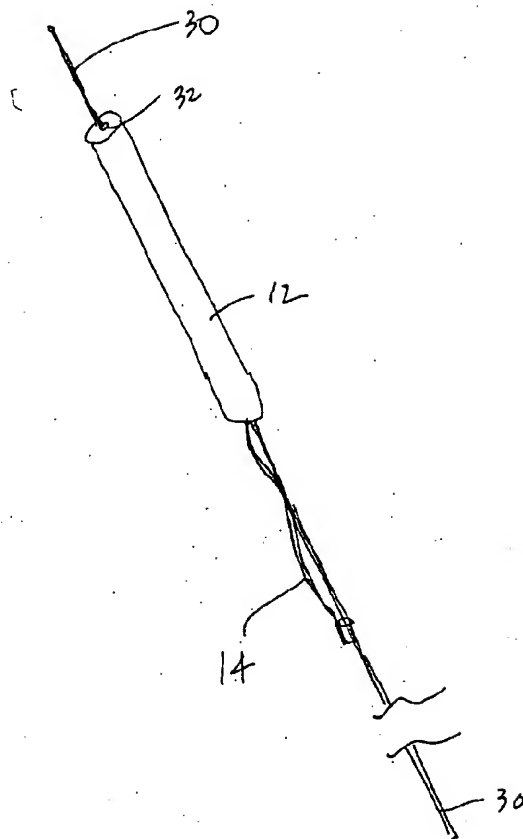


FIG 6

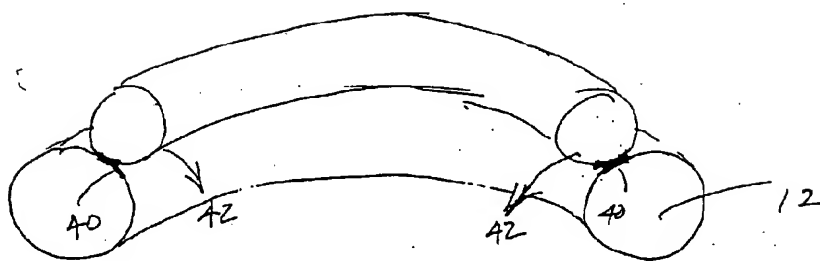


FIG-7A

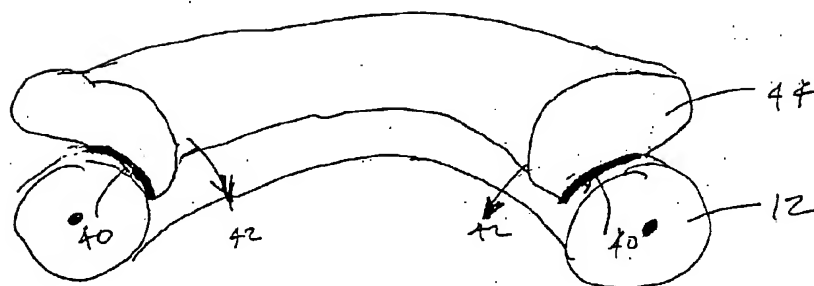


FIG-7B

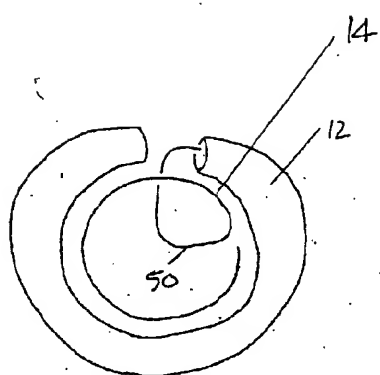


FIG-8A

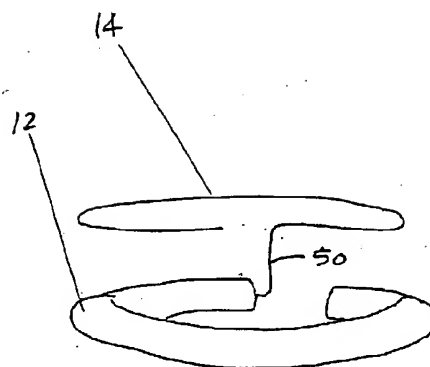


FIG-8B

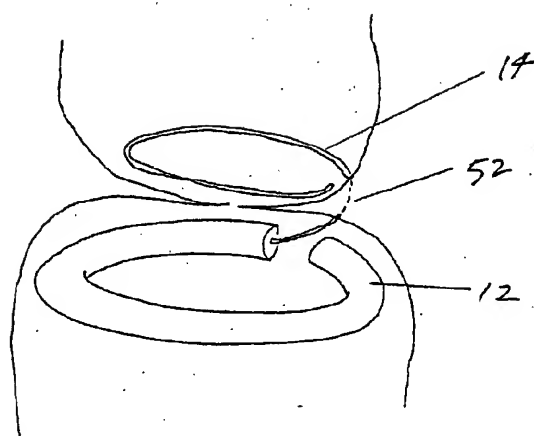


FIG-9



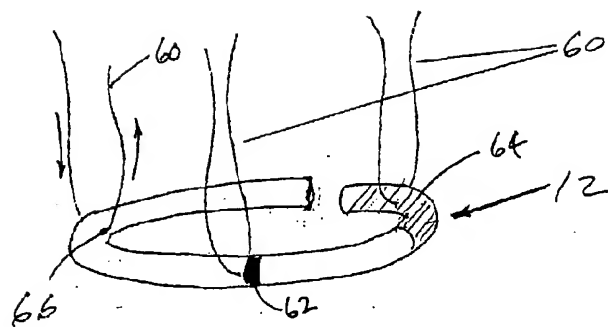
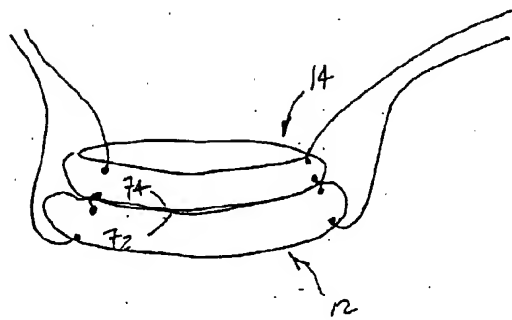
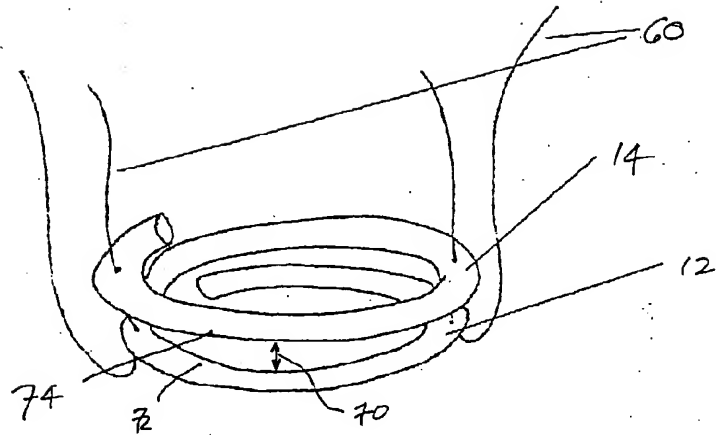


FIG-10A



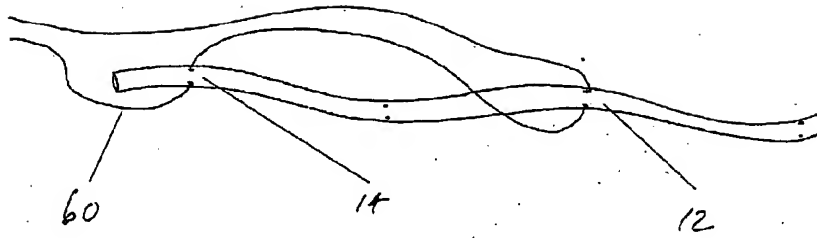


FIG-11

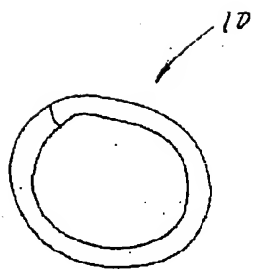


FIG. 12

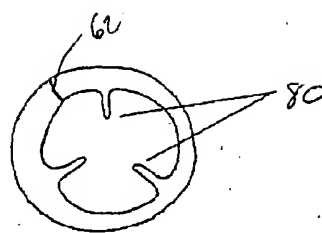


FIG. 13A

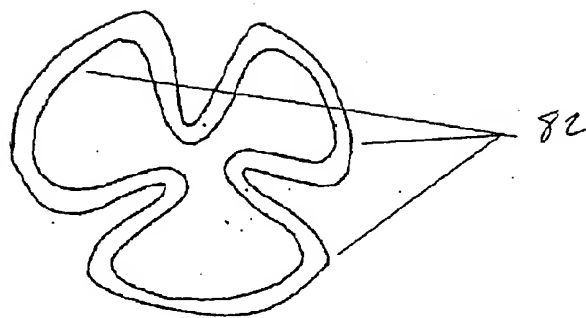
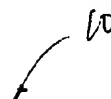


FIG. 13B

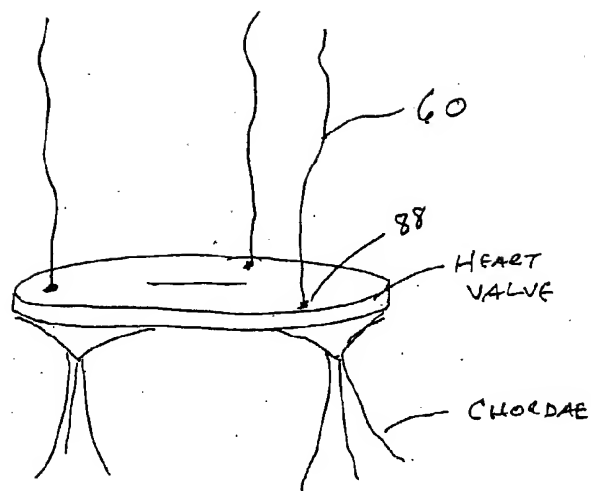


FIG-14A

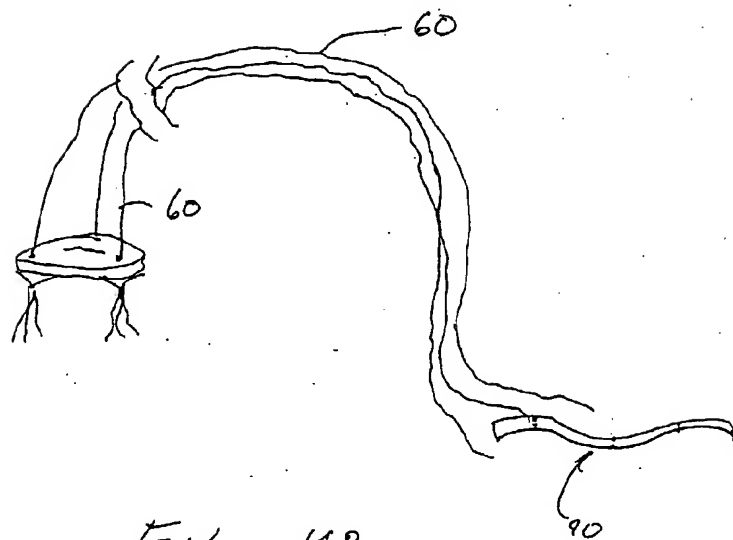


FIG-14B

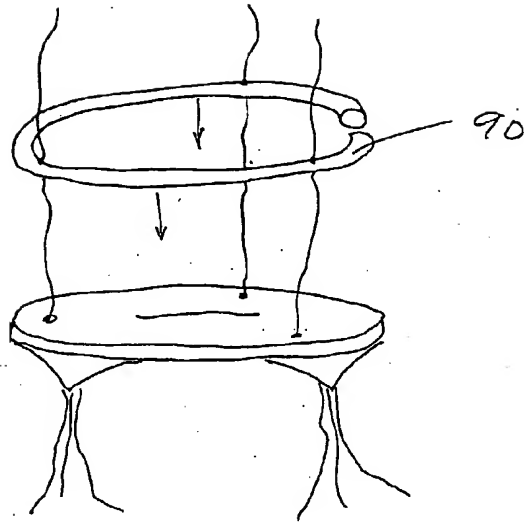


FIG-14C

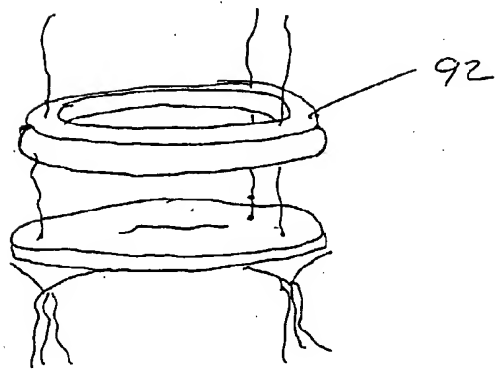


FIG-14D

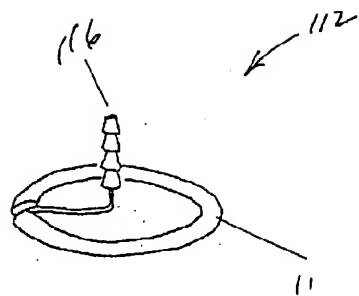


FIG-15A

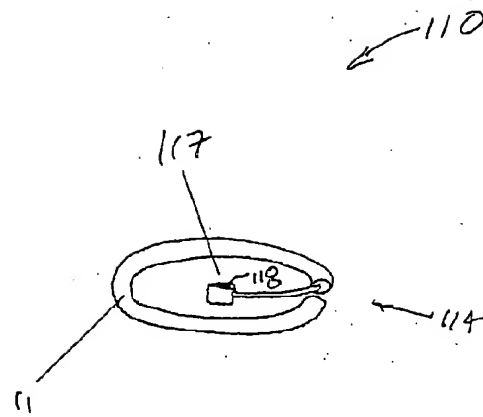


FIG-15B

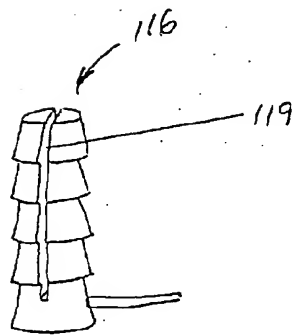


FIG-16

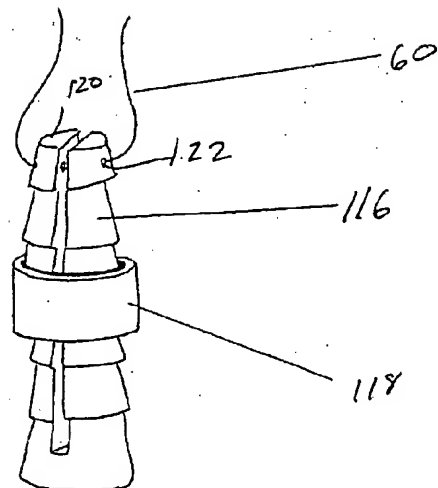


FIG-17

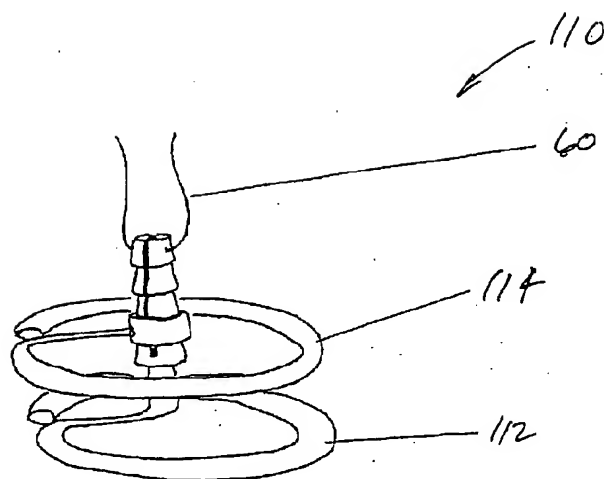


FIG-18



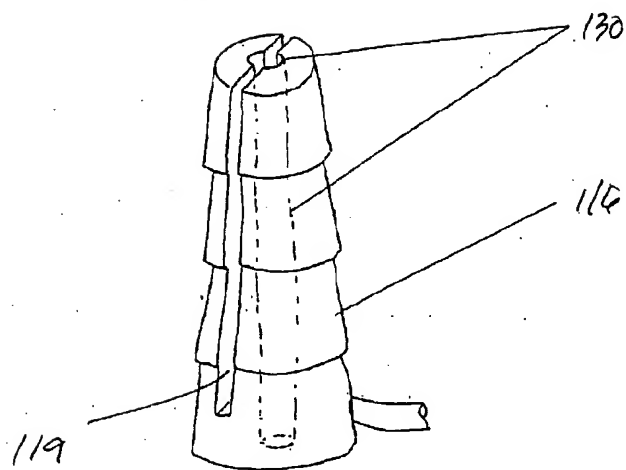


FIG-19

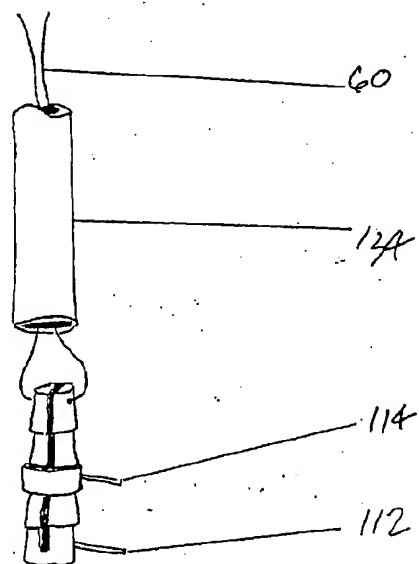


FIG-20

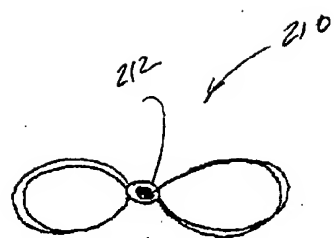


FIG-21

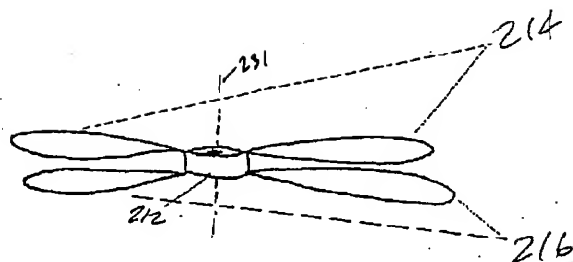


FIG-22

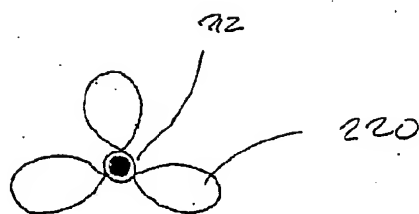


FIG-23

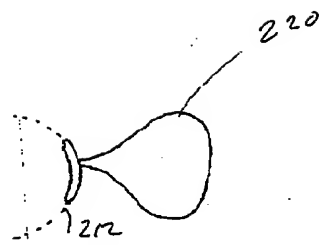


FIG-24

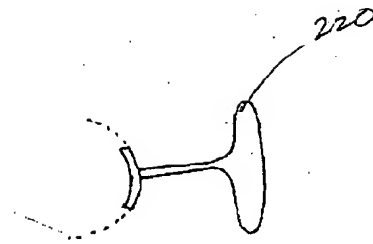


FIG-25

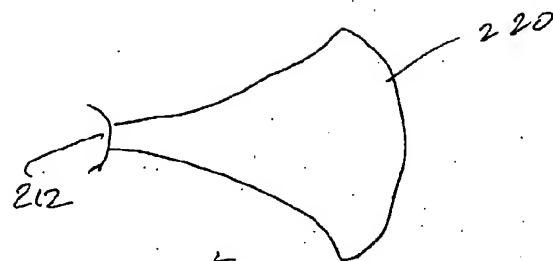


FIG-26

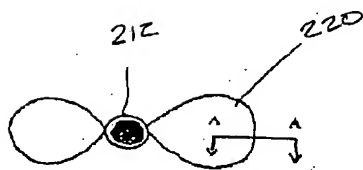


FIG-27A

Rectangular



FIG-27B

Circular



FIG-27C

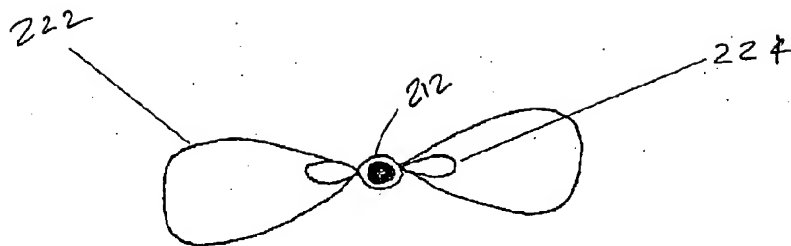
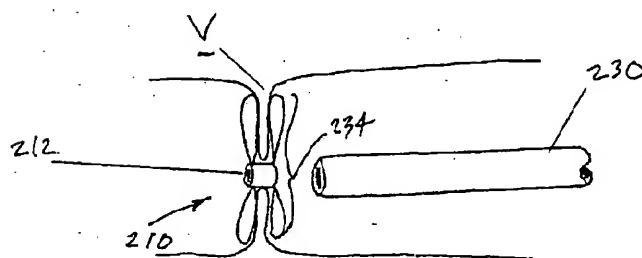
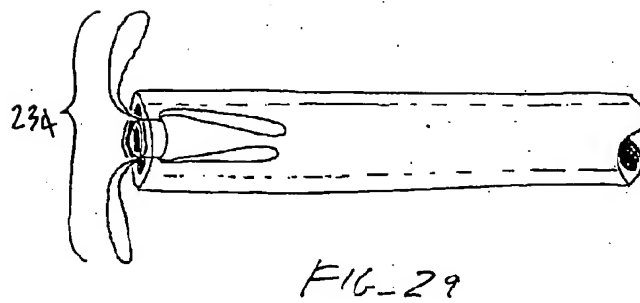
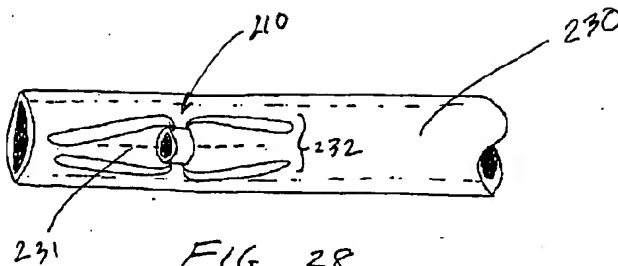


FIG-270



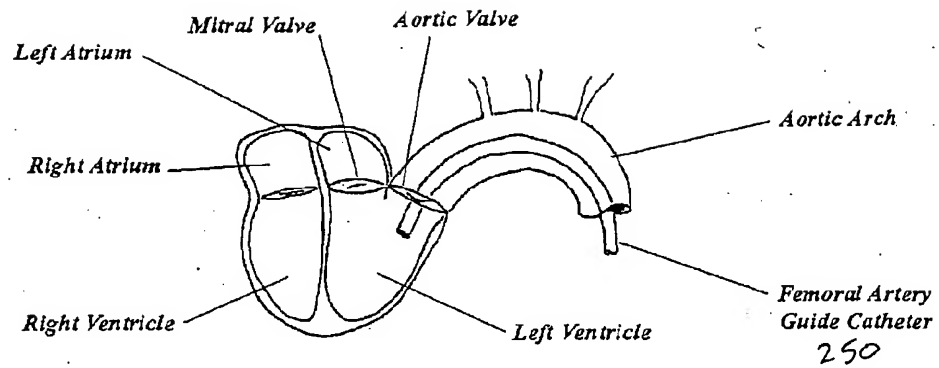


FIG-31

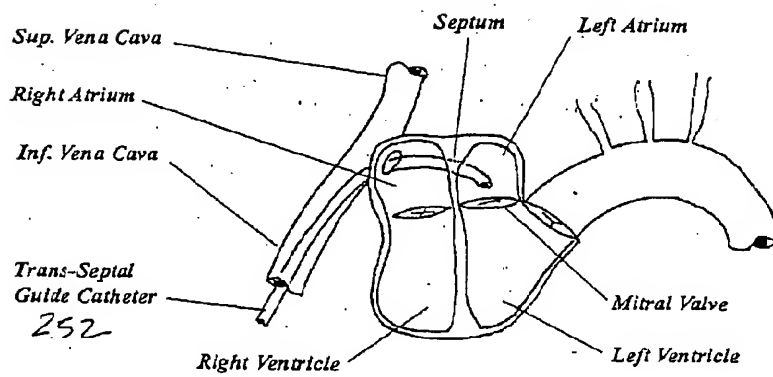


FIG-32

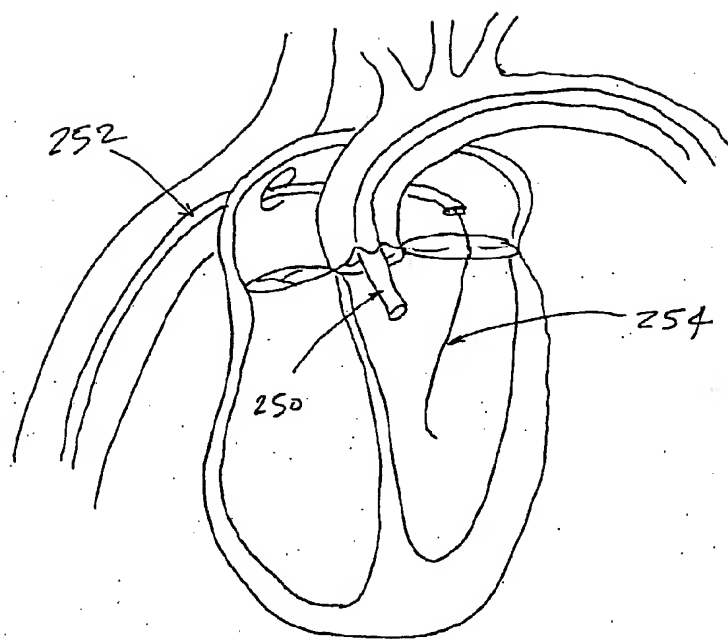
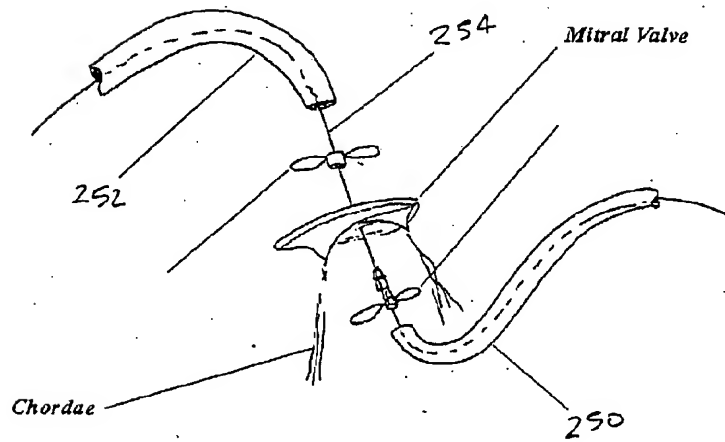
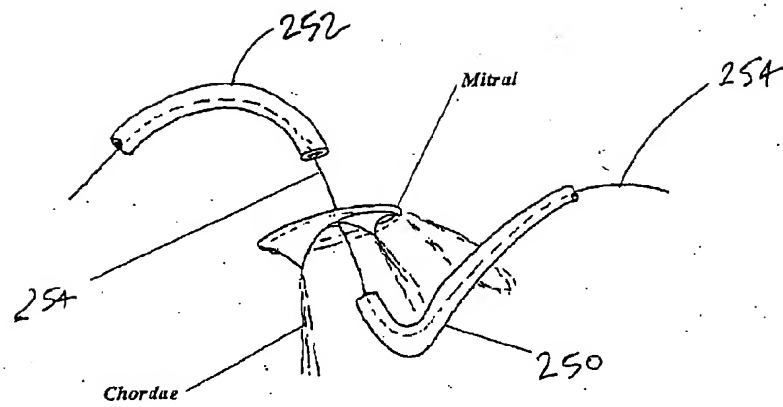


FIG-33





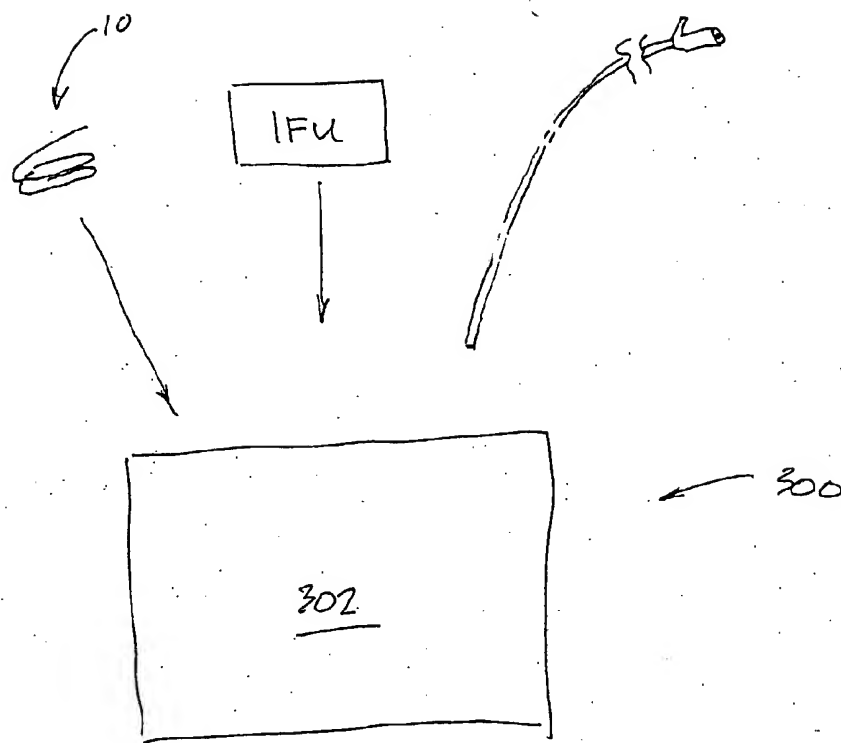


FIG-36

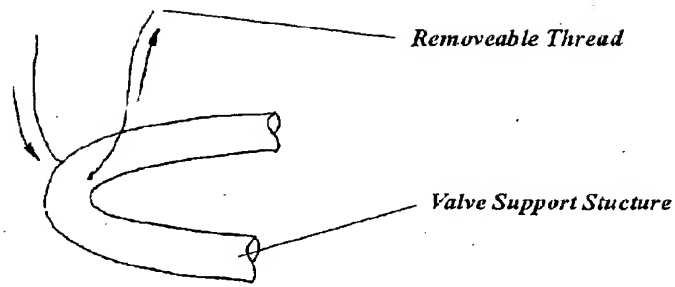


Fig. 37

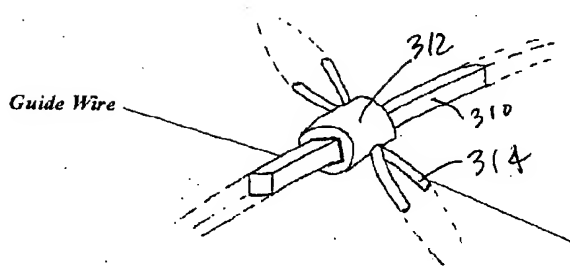


FIG-38

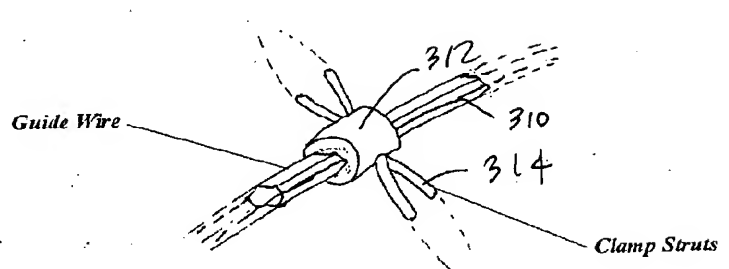


FIG-39

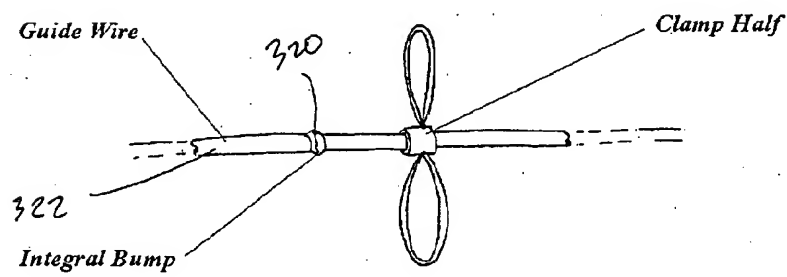


Fig. 40

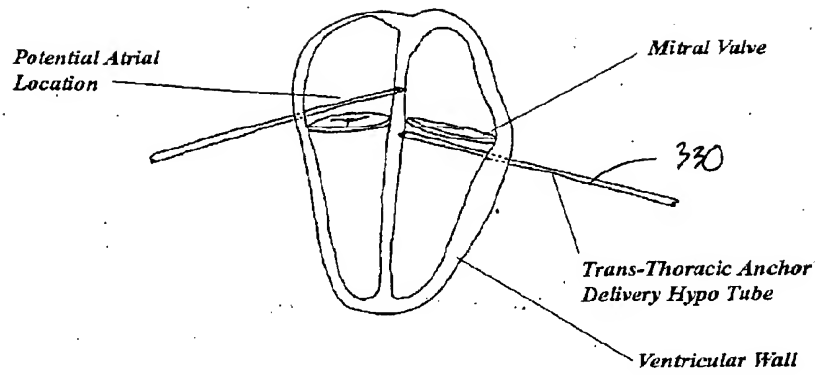


Fig. 41

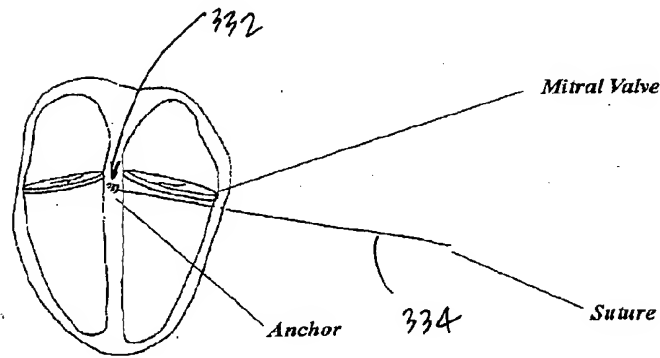


Fig. 42

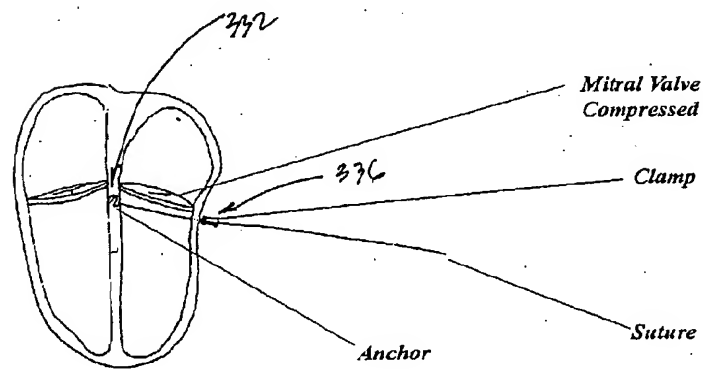


Fig. 43

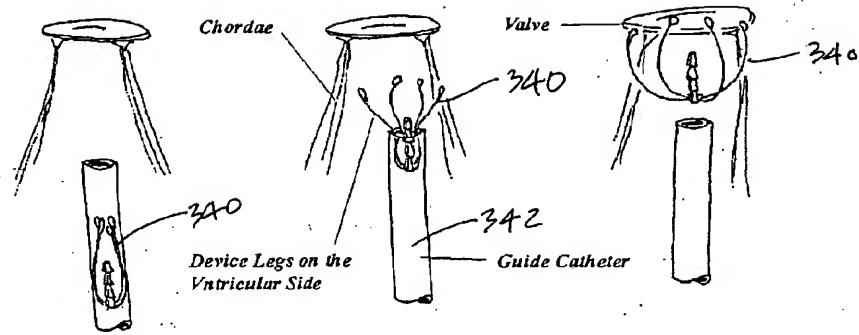


Fig. 44

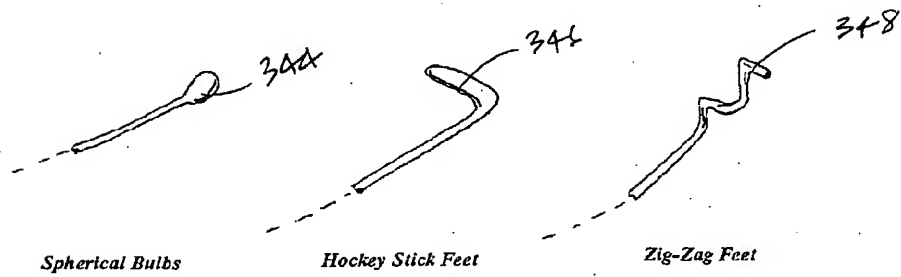


Fig. 45

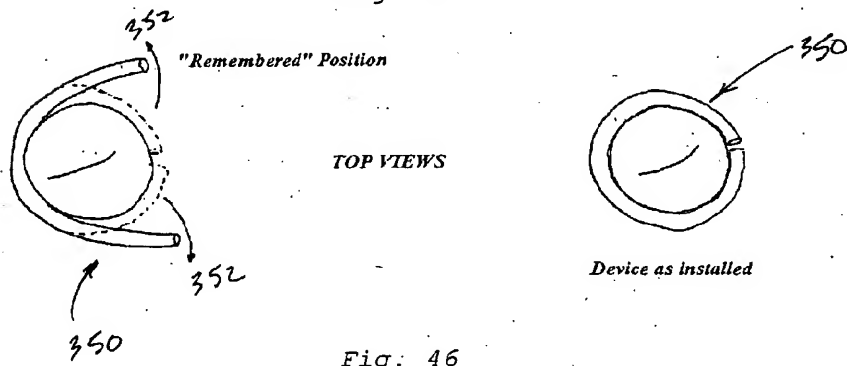


Fig. 46

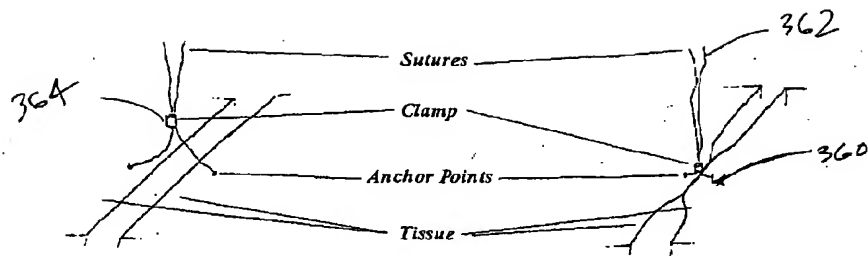


Fig. 47

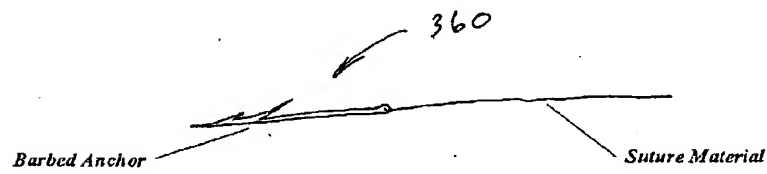


Fig. 48

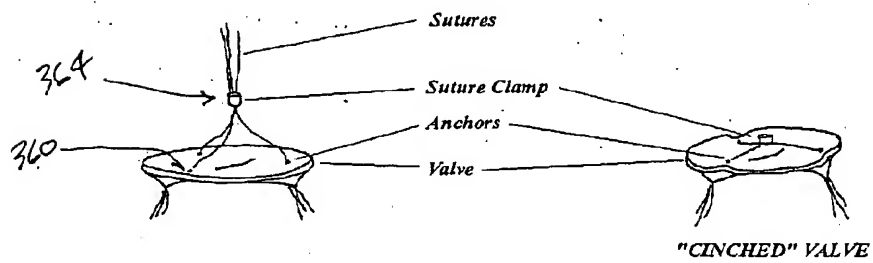


Fig. 49

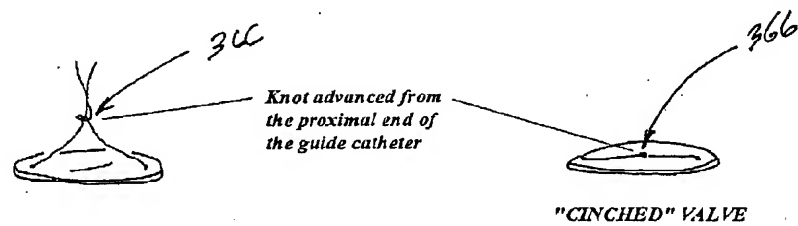


Fig. 50

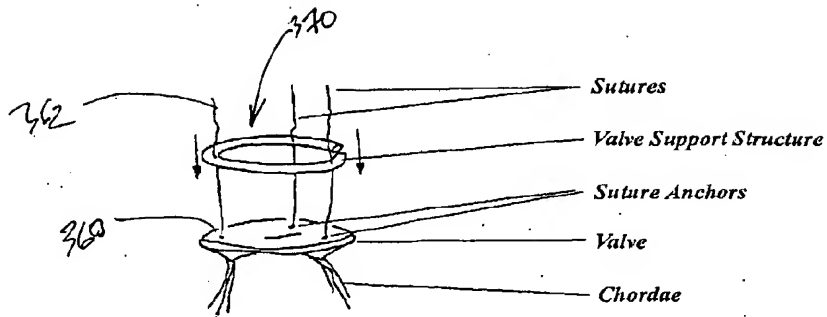


Fig. 51

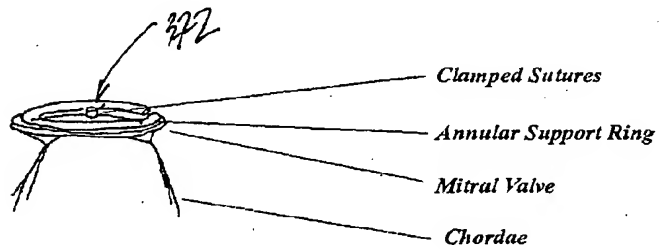


Fig. 52

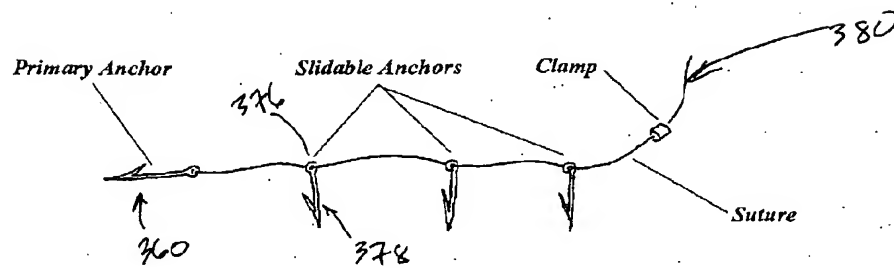


Fig. 53

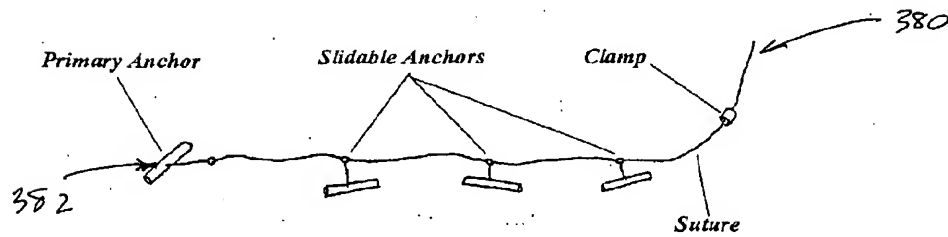


Fig. 54

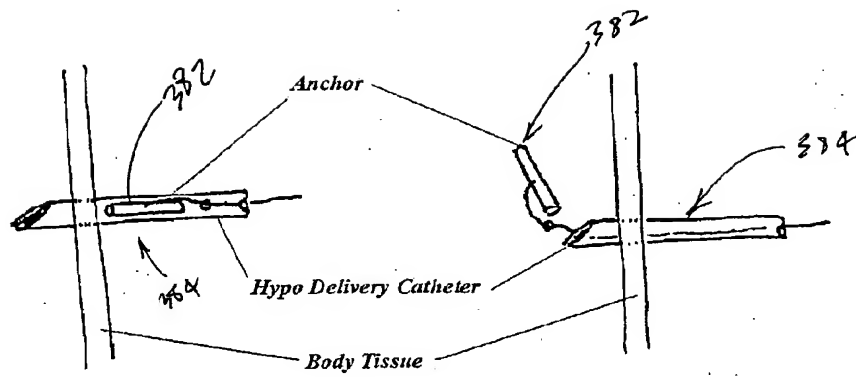


Fig. 55

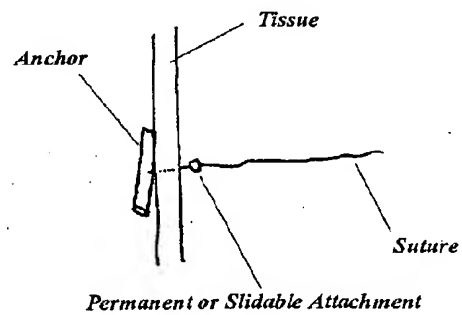


Fig. 56

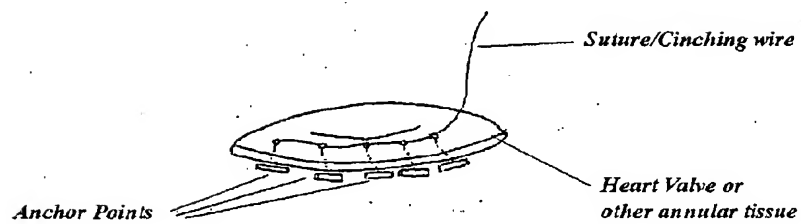


Fig. 57

30/40

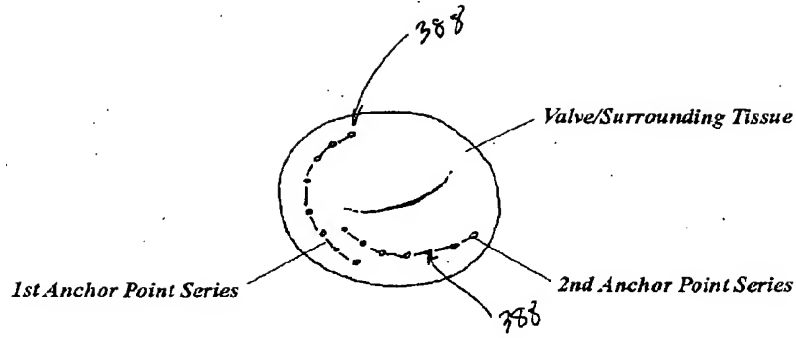


Fig. 58

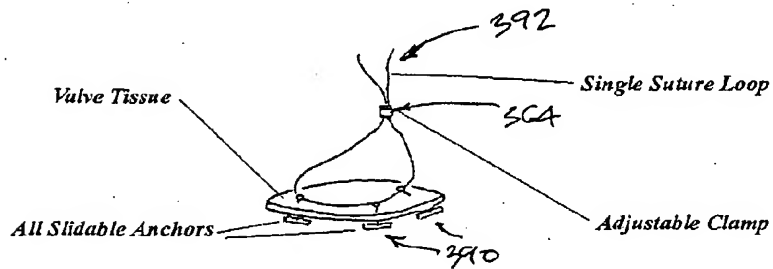


Fig. 59

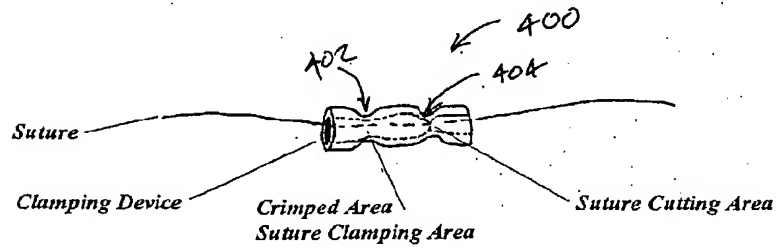


Fig. 60

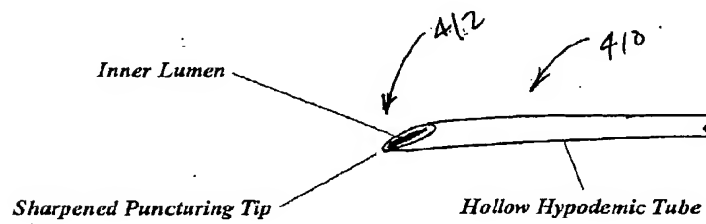


Fig. 61



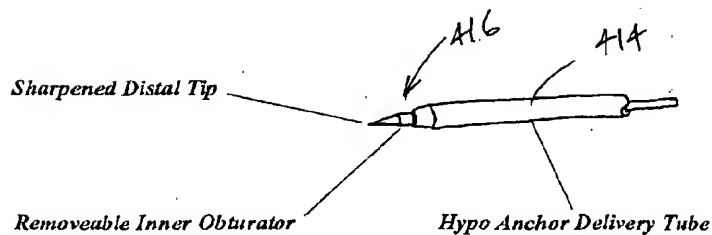


Fig. 62

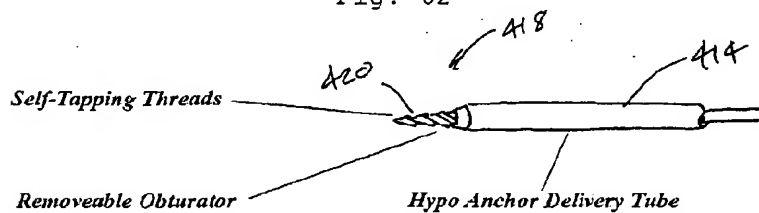


Fig. 63

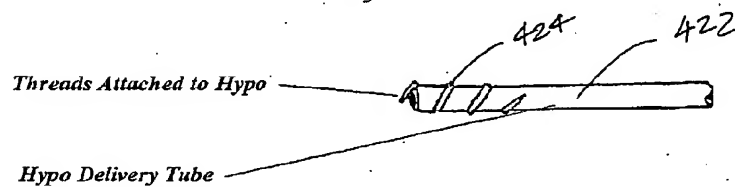


Fig. 64

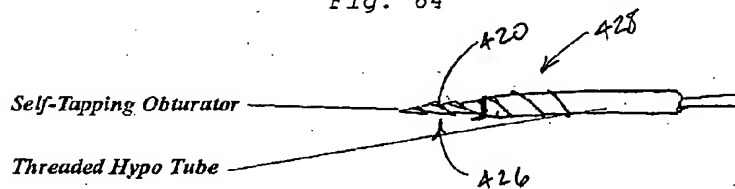


Fig. 65

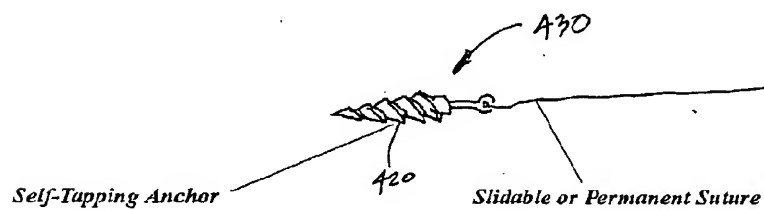


Fig. 66

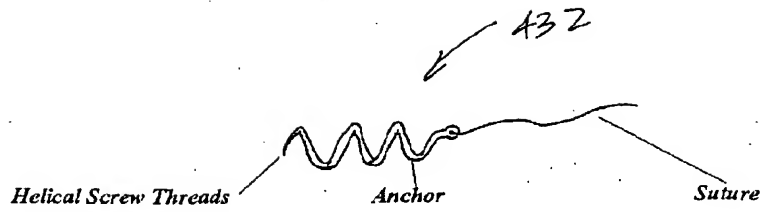


Fig. 67

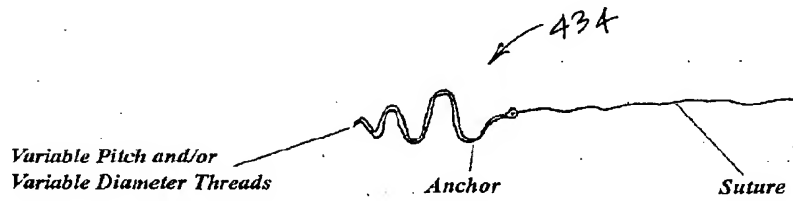


Fig. 68

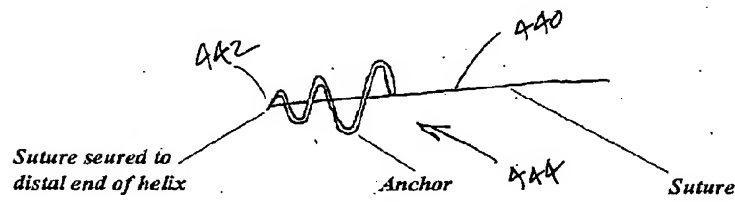


Fig. 69

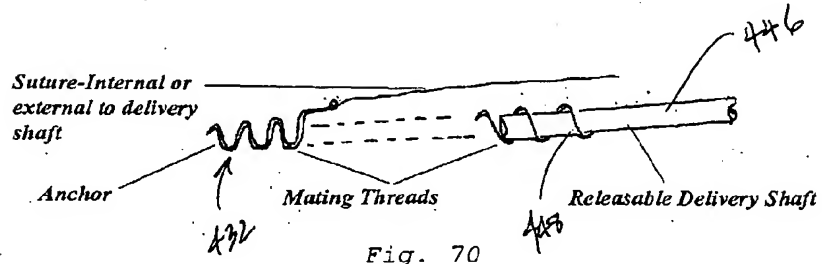


Fig. 70

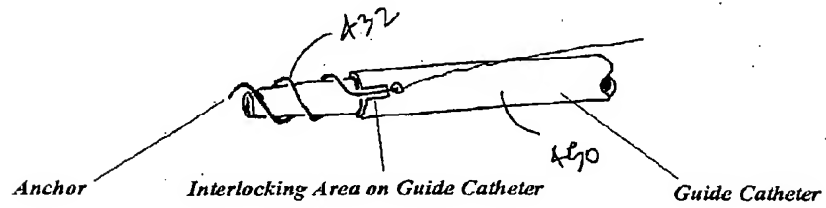


Fig. 71

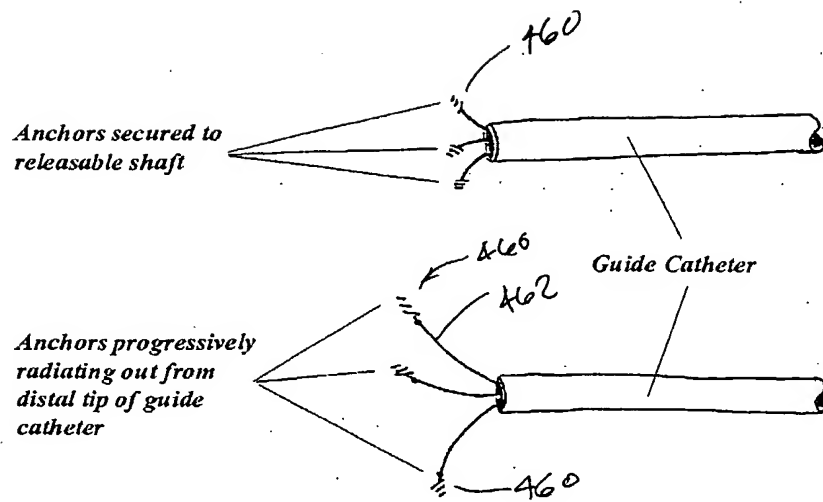


Fig. 72

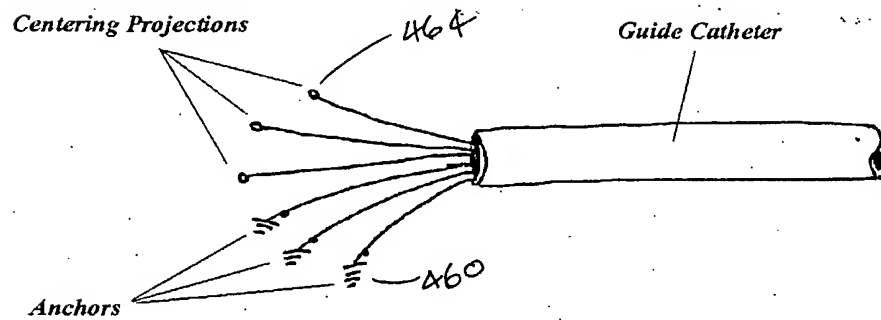


Fig. 73

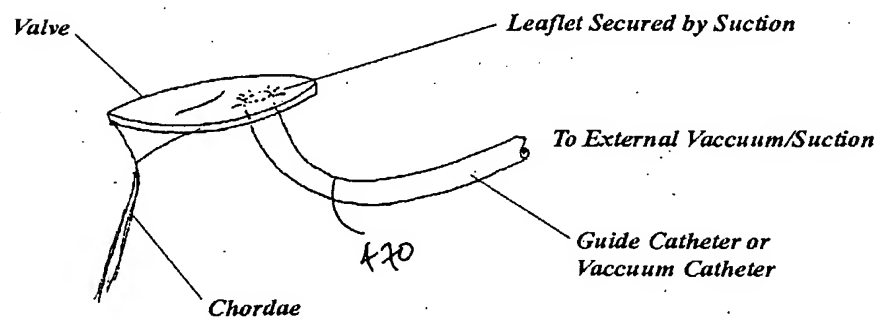


Fig. 74

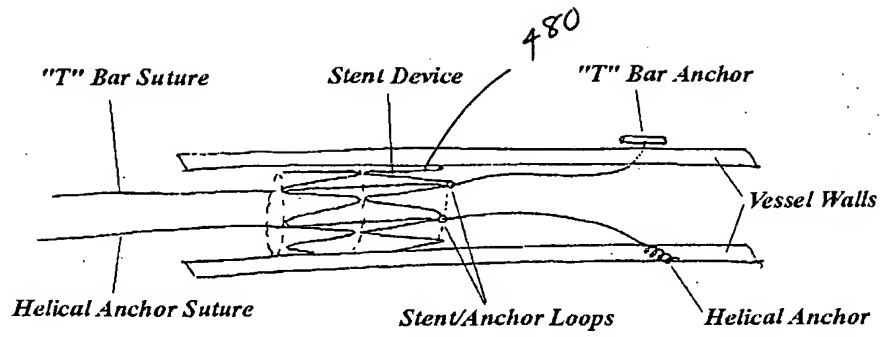


Fig. 75

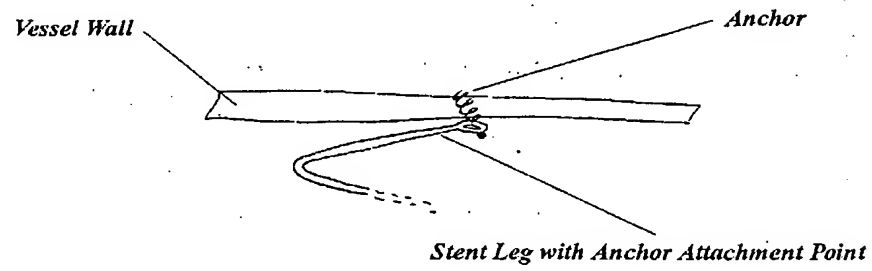


Fig. 76

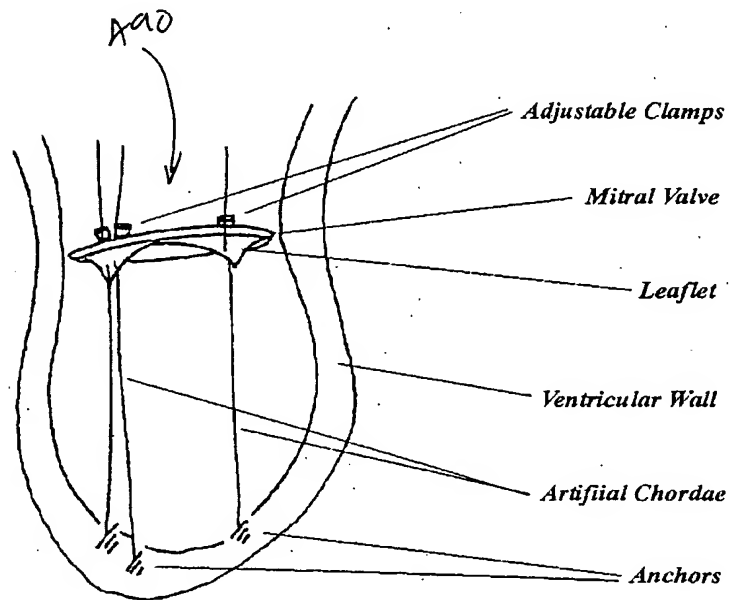


Fig. 77

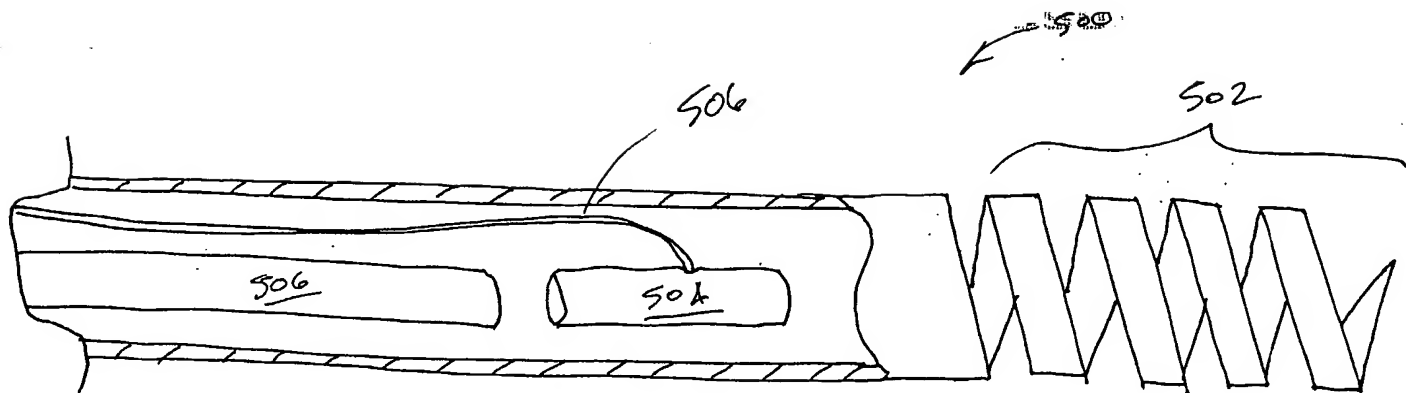
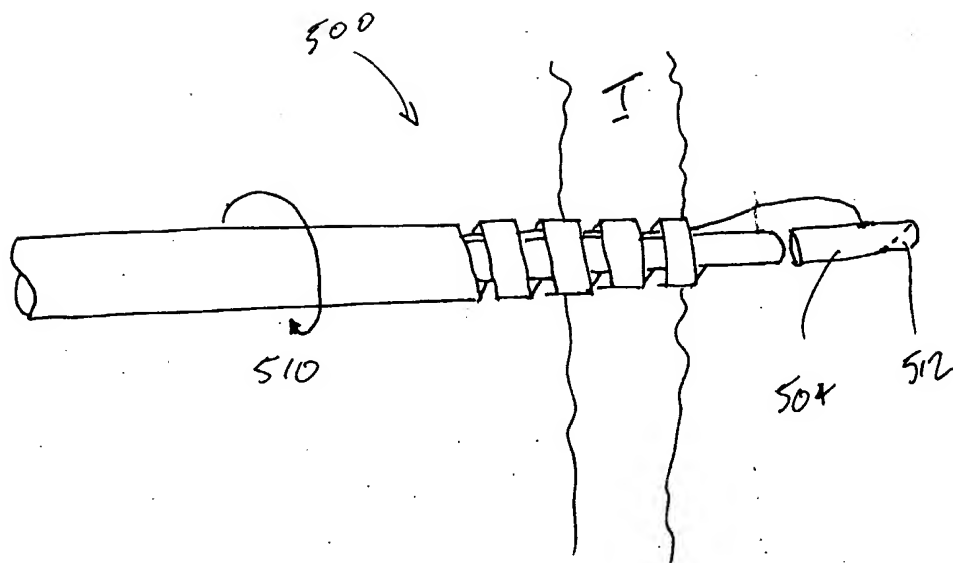
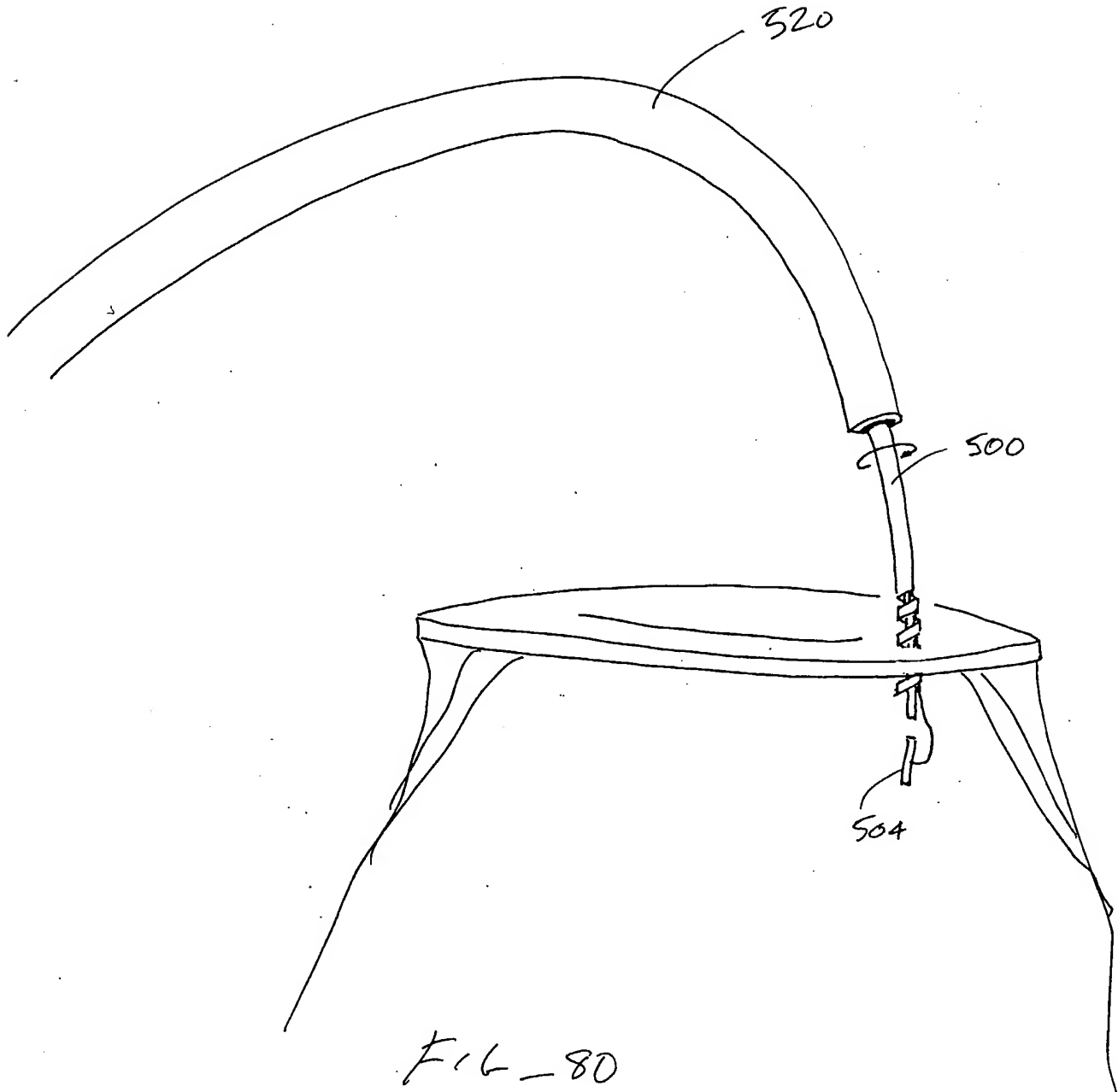


FIG-78



FIG\_ 79



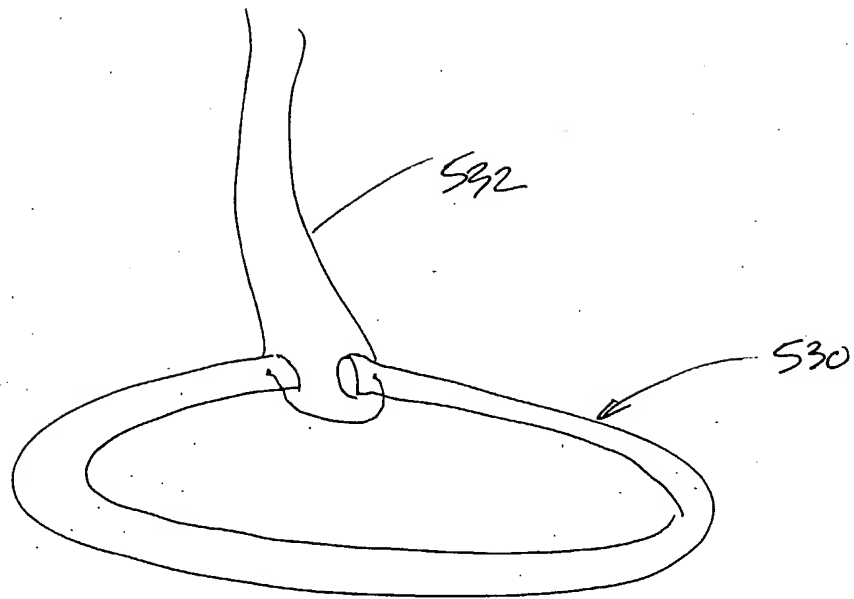


FIG-81

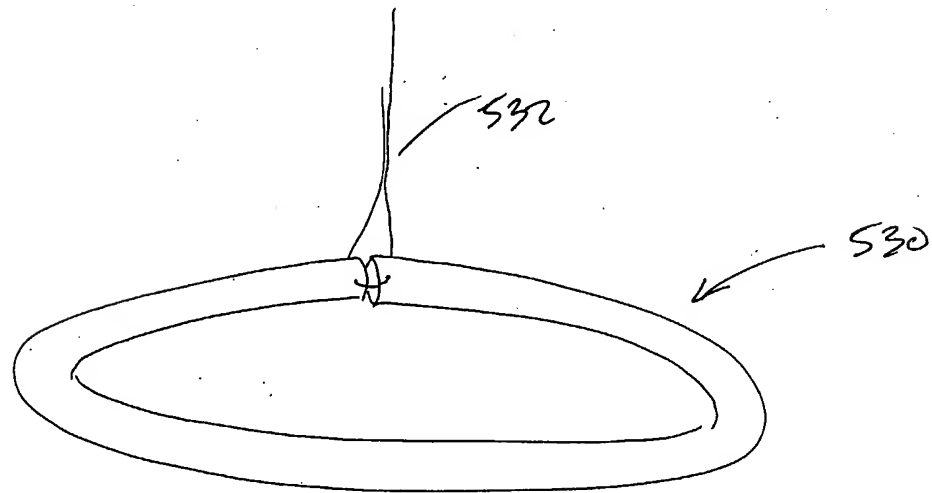


FIG-82



# PFD CLOSURE

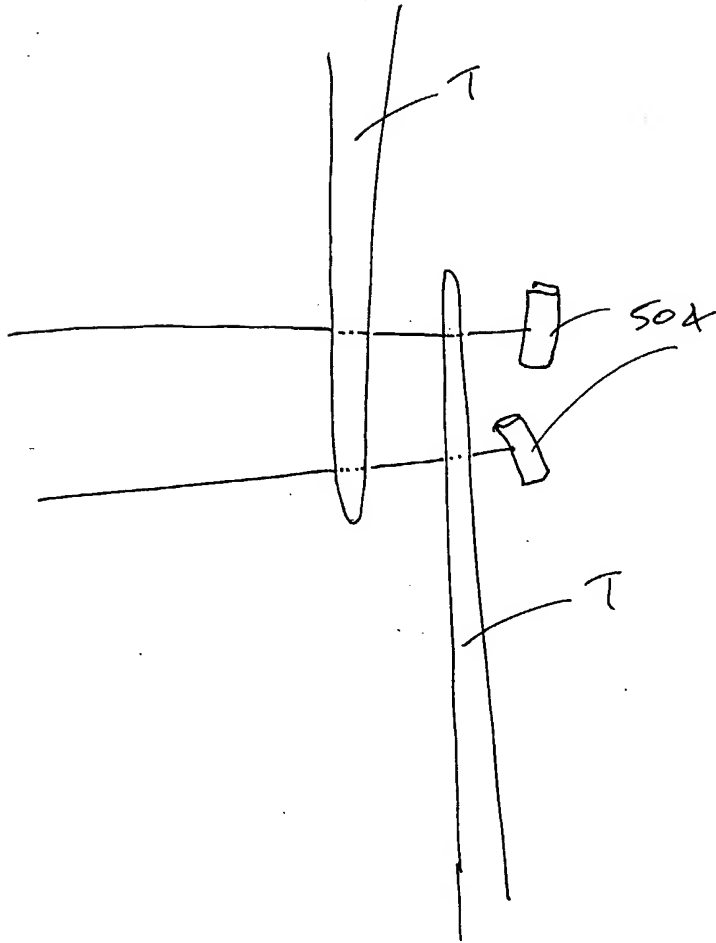


FIG-83

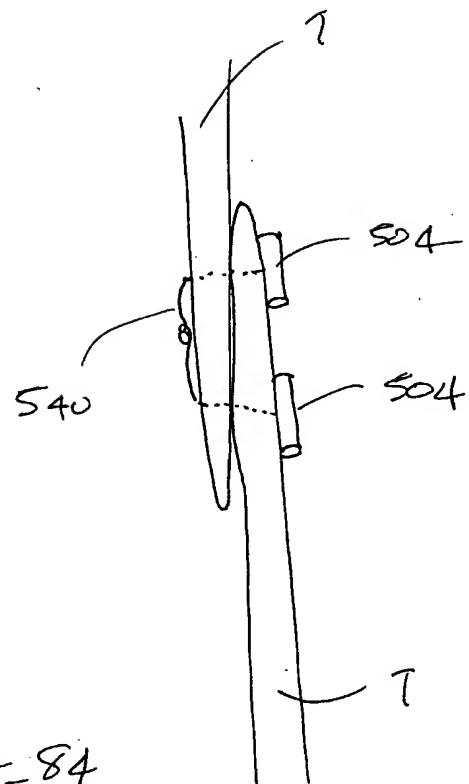


FIG-84

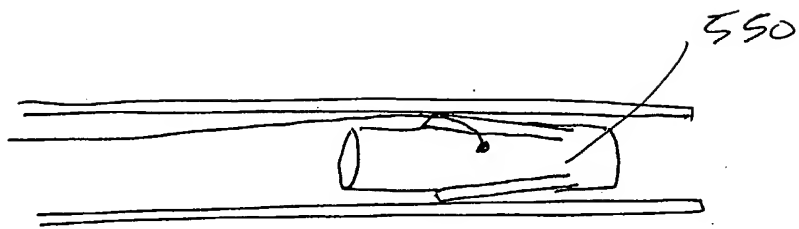


FIG- 85

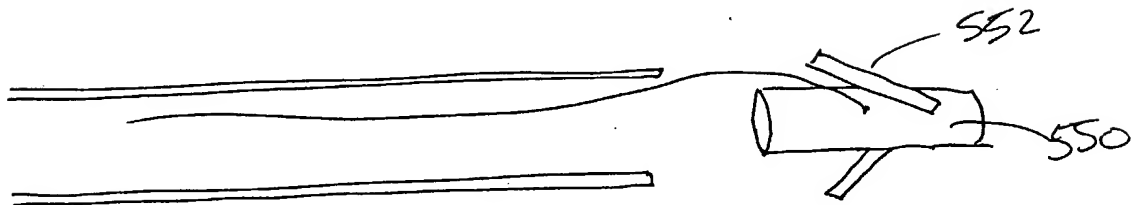


FIG- 86

CORRECTED VERSION

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
24 December 2003 (24.12.2003)

PCT

(10) International Publication Number  
**WO 2003/105667 A3**

(51) International Patent Classification<sup>7</sup>: **A61B 17/00**,  
A61F 2/02

(21) International Application Number:  
PCT/US2003/018749

(22) International Filing Date: 12 June 2003 (12.06.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
60/388,250 12 June 2002 (12.06.2002) US  
10/232,753 30 August 2002 (30.08.2002) US  
10/461,861 12 June 2003 (12.06.2003) US

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(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

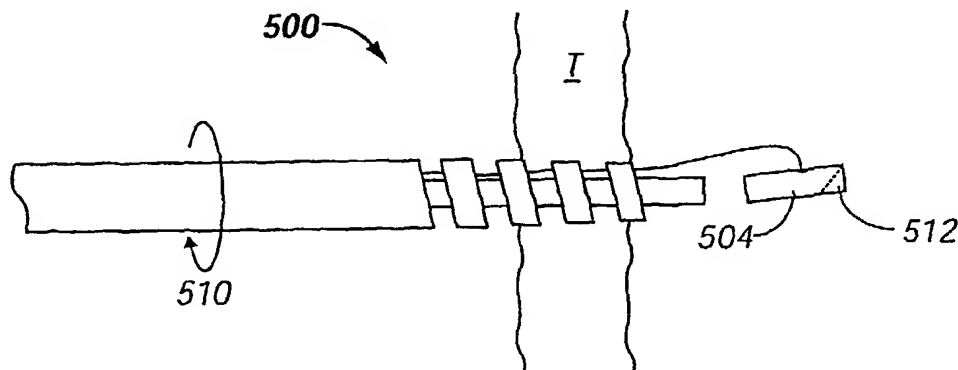
(88) Date of publication of the international search report:  
10 June 2004

(48) Date of publication of this corrected version:  
16 September 2004

(15) Information about Correction:  
see PCT Gazette No. 38/2004 of 16 September 2004, Section II

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHOD AND APPARATUS FOR TISSUE CONNECTION



(57) Abstract: A tissue connecting device is provided. The device comprise an elongate delivery device (502). The distal end is configured to engage tissue and advance the device into tissue. At least one anchor (504) deliverable through a lumen of the elongate delivery device. The distal end of the device may be designed to engage tissue upon rotation of the device about its longitudinal axis.

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## 5                   **METHOD AND APPARATUS FOR TISSUE CONNECTION**

### BACKGROUND OF THE INVENTION

#### Field of the Invention

10               This invention relates generally to medical devices, and their methods of use, and more particularly to devices, and methods of use, utilized for the repair and reconnection of various tissues of the body. The present invention may be useful in a variety of applications including but not limited to minimally invasive devices and methods for repair or reshaping of improperly functioning heart valves or heart tissue.

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#### Description of Related Art

              Bringing together tissues in closer proximity to one another is a typical means for closing wounds such as catheter puncture sites during percutaneous procedures (angioplasty, stenting, endograft procedures and the like), as well as in stomach stapling  
20       for the morbidly obese, gastrostomy placement, etc. Although these procedures all may benefit from the inventions described herein, one particularly useful and immediate benefit for these devices, methods and systems is in the bringing together, or coaptation, of heart valve leaflets so that they close properly against the relatively high pressures during the contraction of the heart muscle so as to improve the pumping efficiency of the  
25       heart muscle. Furthermore, the present invention additionally provides new and novel devices, methods and systems for the percutaneous endovascular repair of the valves of the heart and for their modification and subsequent improvement in cardiac valve function.

              Mitral valve regurgitation is a condition in which the leaflets of the heart valve do  
30       not properly close during contraction (systole) of the heart. This permits blood to flow in a retrograde fashion from the ventricle of the heart back into the atrium of the heart. The pumping efficiency of the heart is compromised and the result, if left unchecked, can be

progressive heart failure resulting in extreme fatigue or worse and the inability of the patient to lead a normal life.

Although there are numerous reasons for damage to the valves of the heart, the typical treatment is often surgery. During surgical repair of the valves, the chest is  
5 usually opened, at least in part, to allow enough room for the surgeon to perform a repair or replacement of the damaged valve. This usually requires that the patient be placed on a bypass machine to pump the blood while the surgeon operates on the stopped heart muscle. For obvious reasons, this can be very traumatic on the patient and recovery may take many months. Additionally, surgery may not be an option for some patients due to  
10 limited possibility for recovery, concurrent disease, or age.

For these reasons, it would be desirable to provide an alternative to open heart surgery to modify, repair or replace a damaged heart valve without requiring the patient's chest to be opened and/or the patient placed on bypass during the procedure.

15

## SUMMARY OF THE INVENTION

The present invention provides new and novel devices, methods and systems for the repair of the valves and for their modification and subsequent improvement in valve function. More specifically, in some embodiments, the present invention achieves these  
20 repairs using percutaneous endovascular techniques that minimize trauma to the patient and provide reduced recovery time and recovery cost.

In one aspect of the present invention, a tissue connecting device is provided. The device comprise an elongate delivery device having a lumen, a proximal end, and a distal end. The distal end is configured to engage tissue and advance said device into tissue. At  
25 least one anchor deliverable through a lumen of the elongate delivery device. The distal end of the device may be designed to engage tissue upon rotation of the device about its longitudinal axis.

In a still further aspect of the present invention, a kit is provided for delivering a tissue connection device to a valve having an annulus and a plurality of leaflets. The kit  
30 may include an elongate member having a first substantially linear configuration when engaged with an elongate delivery device and a second substantially circular configuration defining a first support ring and a second support ring when the member disengages from the delivery device. The kit may further include instructions for use

describing a method for connecting the elongate member to the valve and a package for holding the elongate member and the instructions for use.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

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#### BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is perspective view of an annular support device.

Figures 2-5 illustrate the delivery of the device of Figure 1 to a treatment site.

Figure 6 shows another embodiment of present invention for use with a  
10 straightening mandrel.

Figures 7A and 7B show cross-sectional views of interaction between two support rings to engage tissue therebetween.

Figure 8A and 8B are top and side views of another annular support device.

Figure 9 shows the device of Figure 1 penetrating tissue.

15 Figures 10A-10C show the use of sutures on annular support rings in accordance to the present invention.

Figure 11 shows the attachment of sutures to a support ring in a linear configuration.

Figures 12-13B show various geometries of the support ring.

20 Figures 14A-14D illustrate the use of a support ring and sutures at a tissue site.

Figures 15A-20 show embodiments of the present invention using separable clamping portions.

Figures 21-27D illustrate varying geometries of leaflet clamps for use with the present invention.

25 Figures 28-30 show the delivery of an apparatus according to the present invention with deflectable leaflet clamps.

Figures 31-35 illustrate positioning of delivery devices to reach a treatment site in the heart.

Figure 36 shows a kit containing an annular support ring and accessories.

30 Figure 37 shows a suture coupled to a support member.

Figures 38-40 show clamps for used with shaped guide wires.

Figures 41-43 show delivery of anchors into tissue.

Figures 44-52 show additional techniques for delivering support devices to tissue.

Figures 53-60 show various anchor embodiments according to the present invention.

Figures 61-73 show various anchor and delivery devices for use in piercing tissue.

Figures 74-77 show additional uses of embodiments of the present invention.

5       Figures 78-86 show still further embodiments of delivery devices and anchors according to the present invention.

#### DESCRIPTION OF THE SPECIFIC EMBODIMENTS

It is to be understood that both the foregoing general description and the following  
10       detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed. It may be noted that, as used in the specification and the appended claims, the singular forms “a”, “an” and “the” include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to “a material” may include mixtures of materials, reference to “a chamber” may include multiple chambers, and the  
15       like. References cited herein are hereby incorporated by reference in their entirety, except to the extent that they conflict with teachings explicitly set forth in this specification.

In this specification and in the claims which follow, reference will be made to a number of terms which shall be defined to have the following meanings:

“Optional” or “optionally” means that the subsequently described circumstance  
20       may or may not occur, so that the description includes instances where the circumstance occurs and instances where it does not. For example, if a device optionally contains a feature for analyzing a blood sample, this means that the analysis feature may or may not be present, and, thus, the description includes structures wherein a device possesses the analysis feature and structures wherein the analysis feature is not present.

25       The present invention provides new and novel devices, methods and systems for the repair of a valve and for their modification and subsequent improvement in valve function. More specifically, in some embodiments, the present invention achieves these repairs using percutaneous endovascular techniques that minimize trauma to the patient and provide reduced recovery time and cost. One particularly useful and immediate  
30       benefit for these devices, methods and systems is in the bringing together, or coaptation, of heart valve leaflets so that they close properly against the relatively high pressures during the contraction of the heart muscle so as to improve the pumping efficiency of the heart muscle.

In the various embodiments, the devices, methods and systems of the present invention provide connection and/or reconnection of body tissues, whether disconnected by trauma, surgery, disease, normal anatomy, or other means., although the devices described herein may, in fact, be used during open-heart surgery or minimally invasive heart surgery. By way of illustration, and without limitation, the devices, methods and systems are useful for the repair of the atrioventricular valves of the heart, particularly the mitral valve. In one embodiment, it may be desirable to perform the repair endovascularly, advancing the devices and systems through the major blood vessels leading to and exiting from the heart, and using these conduits as natural pathways for the devices to access the valves of the heart. Although the repair of the mitral valve will be discussed in detail, it can be appreciated that the devices, methods and systems described herein can easily be adapted to repair, connect, or bring other various body tissues into closer proximity to one another. At least some of these objectives will be met by the novel inventions, devices, methods and systems described hereinbelow. Those skilled in the art will immediately recognize that various combinations, modifications, and equivalents of the inventions described herein can be used without departing from the scope of these inventions.

Referring now to Figure 1, in one embodiment of the present invention, a tissue connection device 10 suitable for minimally invasive delivery comprises a first support ring or annular support ring 12 and a second support ring or attached clamp 14 that secures the ring 12 to the opposite sides of the valve tissue. The first support ring 12 provides support for the annular ring of tissue surrounding the heart valve or other target site so that proper coaptation may occur with the valve leaflets (see Figure 5). As seen in the embodiment of Figure 1, the first support ring 12 may be substantially in a first plane while the second support ring 14 may be substantially in a second plane roughly parallel to the first plane.

Referring now to Figure 2, delivery of the device 10 may be accomplished by straightening the first support ring 12 and second support ring or clamp 14 and inserting device 10 through an elongate delivery device 20 such as, but not limited to, a guide catheter that may be used to access the chambers of the heart. As seen in Figure 2, the device 10 is an elongate member that assumes a substantially linear configuration when placed inside an appropriately sized guide catheter. In one embodiment, the guide catheter may be sized between about 3 and 15 French (1mm to 5mm diameter). When the



device 10 is removed from the delivery device 20, the tissue connection device 10 may assume a coiled configuration as shown in Figure 1.

Referring now to Figure 3, the delivery device 20 such as a guide catheter may be inserted at a location remote from the heart such as the femoral artery, brachial artery,  
5 inferior vena cava, jugular vein, etc. In this example, delivery device 20 is then advanced through the vessel to the heart and across the target valve. As the device 10 in a straightened ring or linear configuration is advanced out the distal end of the catheter, the device 10 begins to regain its pre-formed coil or circular shape.

Referring now to Figure 4, following deployment of the first support ring 12, the  
10 delivery device 20 is pulled back to the proximal side of the valve where the clamp portion or second support ring 14 of the device 10 is deployed.

As seen in Figure 5, the tissue connection device 10 when deployed in the heart valve captures a tissue T between the first support ring 12 and the second support ring 14. The clamping action of device 10 reduces the dilation of the valve formed by tissue T,  
15 thus urging the leaflets closer to the center of the valve. It should be understood that, in some embodiments, configuration may be reversed where the second support ring 14 is on the bottom of the valve and the first support ring 12 is located on top. Furthermore, as seen in Figures 1-5, the first support ring 12 may be thicker or have a greater radial thickness than the radial thickness of the second support ring 14. The greater radial  
20 thickness may provide improved support or capture to tissue engaged between the rings. Additionally, the second support ring 14 having a smaller radial thickness may be more easily situated on sides of the valve with chordae or other materials that may interfere with proper device seating. Still further, as discussed for Figures 7A and 7B, the varying thicknesses may also provide a desired reshaping of tissue captured between the rings 12  
25 and 14 to reduce dilation of the valve tissue.

Referring now to Figure 6, in another embodiment of the present invention, the device 10 may be configured for use with a straightening mandrel 30 that is used as a delivery device 20 to deploy the device 10 to the target site. As seen in Figure 6, the straightening mandrel 30 may pass through a lumen 32 in the first support ring 12 and a  
30 guide loop on the second support ring 14. Thus in this embodiment, the tissue connection device is constrained through internal straightening parts instead of externally constraining parts when a guide catheter is used. The device 10 is loaded onto a straightening mandrel 30 or guide wire for delivery and upon removal of the mandrel or

guide wire, the annuloplasty ring and/or clamp reverts back to its pre-determined remembered shape, typically in its valve supportive configuration. The hollow device 10 and its removable straightening guide wire/mandrel are also adaptable for use with each of the other designs described within this specification, and is not limited to just the  
5 annuloplasty ring and clamp configurations.

Referring now to Figures 7A and 7B, another embodiment of the present invention will now be described. For ease of illustration, the rings are shown to be touching. It should be understood that tissue may be engaged between the rings and captured therebetween. In the embodiment of Figure 7A, the first support ring 12 has a  
10 larger circumference than the second support ring 14. The ring 14 engages an inner circumferential surface 40 of the first support ring 12. This provides a radially inward force as indicated by arrows 42 on a tissue captured between the rings. The outer ring, in this case first support ring 12, may engage the tissue first and then the second ring 14 will engage the tissue and pull it inward. For heart valve reshaping, this will bring the  
15 valve leaflets closer to the center and reduce dilation of the valve minimize leakage and regurgitation.

Figure 7B shows another embodiment where the ring 44 has substantially the same diameter or circumference as the first support ring 12. The ring 44, however, has a cross-sectional geometry wherein the ring 44 only engages the inner circumferential  
20 surface 40 of the first support ring 12. Again, the rings will draw tissue radially inward as indicated by arrows 42.

Referring now to Figures 8A and 8B, the connection between the support ring 12 and the clamping ring 14 may have variations depending on the valve anatomy, location, and disease condition. For instance in one embodiment, it may be desired to have the  
25 connection between the two structures in the center of the valve such that there is no interference with the movement of the valve leaflets (Figures 8A and 8B). A portion 50 of the tissue connection device will be configured to extend through the center of the valves.

Referring now to Figure 9, an alternative embodiment of the present invention has  
30 a portion 52 of the elongate member that transverses through the leaflet tissue towards its most outer edge where there would be little or no interference with the valve leaflet. Additionally, this position for the connection would allow the entire device to remain out of the flow of blood through the valve opening. This would have the advantage of no

disruption of blood flow through the valve and minimizes bloodstream turbulence and the potential formation and/or dislocation of blood clots around the device.

Referring now to Figures 10A through 10C, to aid in the proper seating or apposition of the valve annular support structure against the valve tissue, detachable  
5 threads or sutures may be attached at various points around the device. As seen in Figure 10A following deployment of the distal structure, whether first support ring 12 or second support 14, the threads or sutures 60 may be pulled proximally towards the guide catheter, thereby properly seating the structure to the underside of the valve. At least one thread or suture 60 would aid in proper seating, preferably three, so that the orientation of the  
10 structure could be adjusted against the valve. The location of each thread or suture 60 on the structure may be identified with unique radiopaque markers 62 to help in the choice of which part of the structure and which corresponding thread needs additional tension for optimum valve support. After positioning the device 10 but before permanent deployment, the improvement in valve function may be assessed. Valve function may be  
15 assessed by any suitable means such as angiography, magnetic resonance imaging, ultrasound imaging, trans-esophageal echocardiography and the like. Following verification of improved valve function, one end of the releasable thread could be pulled, removing the thread from its connection to the valve support structure. (See Figure 37 for removal of thread.)

20 Materials used in the construction of the annular support ring 12 or the second support ring/clamping device 14 include, but are not limited to, Nitinol, superelastic metallic alloys and plastics, PTFE, silicone, stainless steel, ceramics and/or other suitable materials or combinations thereof. Additionally, shape-memory alloys and plastics may be used for the support structure and/or the clamping structure in order for the device to  
25 be delivered in a straightened condition and, when heated to a temperature above its transition temperature, the valve support structure and/or the clamping structure assume their predetermined geometries. In one embodiment, the temperature of the body would be sufficient to transform the shape of the shape-memory material into its ring and clamp configuration. In another embodiment, energy is applied to the device using electrical,  
30 radio frequency, microwave, heated solutions passed through the guide catheter, or other suitable energy source to transform the shape-memory material to its remembered clamping and support shape. Still further, the exterior surface of the first support ring 12 or second support ring 14 may be conditioned to accept penetration or engagement with a

needle carrying a suture. As seen in Figure 10A, the surface may have a mesh or other covering 64 to facilitate coupling with sutures 60. The mesh may be made of a variety of materials such as Dacron® or other suitable material. For ease of illustration, only a portion of the ring 12 is shown to be covered with mesh, though it should be understood that the entire ring may be covered with mesh. Other methods may also be used to facilitate such eyelets, apertures 66, anchoring locations, or connection devices on the ring 12. The ring 12 may also be made entirely of a penetrable material so that sutures may be easily placed in the device. The ring material may also be made porous in order to promote endothelialization of the ring around the valve. A more secure device may aid in the support the implantable ring provides to the valve tissues. Suitable materials for the ring include Nitinol, ceramics, and plastic polymers. Additionally the materials used may elude drugs that may assist in the promotion of endothelialization. Alternatively, the ring may be surrounded by materials such as polyester that promotes tissue ingrowth and endothelialization of the device.

Referring now to Figure 10B, in another embodiment of the device 10, sutures 60 may be secured to both the first support ring 12 and the second support ring 14 such that, when in its desired position, the sutures apply additional force to the rings 12 and 14 in order to increase the clamping force between the two structures and provide additional support to the valve's annular ring. When delivered, the first support ring 12 and second support ring 14 are spaced apart by a distance 70, wherein a first ring tissue engaging surface 72 is separated from a second ring tissue engaging surface 74.

To secure the clamp section 14 and the support section 12 together, a knot and/or a clamp (or alternate securing means) for each suture 60 is advanced from outside the body, through a guide catheter, and to the device using any one of several knot-tying techniques and/or tools commonly used in vessel closure devices. Additionally, a portion of the suture material 60 may be elastic in order to provide a constant force to the support structure so that during the normal contractions of the heart, the device 10 is allowed limited movement relative to the valve. As seen in Figure 10C, the device 10 when sutured together may engage tissue captured between surfaces 72 and 74 to reform the valve tissue as desired.

Referring now to Figure 11, the device 10 as delivered through a guide catheter 20 with sutures attached, would look similar to the referenced illustration. Each of the pre-threaded sutures 60 attached to the ring structure 12 line up with the corresponding points

on the clamp 14 that are located immediately adjacent to the ring attachment points when in its delivered configuration. This facilitates placement and clamping of the device 10.

Referring now to Figure 12, the standard ring-shaped coil device 10 described is only one configuration that may be delivered in a straight configuration and provide  
5 support for the valve or target tissue when delivered to its destination. Other shapes may provide additional support for one or more leaflets of the valve or may provide additional support to a damaged portion of the heart valve annulus. For example in Figure 13A, inner extensions 80 on the ring may provide a backboard for the leaflets preventing prolapse of the valve leaflet during systole of the heart. In another embodiment as seen in  
10 Figure 14B, the ring 12 may be shaped more like a bi-lobed leaf for the mitral valve, or a shamrock or cloverleaf configuration 82 for the three-leaflet tricuspid valve of the heart. The additional inner structure(s) of the cloverleaf configuration 82 provides the valve leaflet with an area that it cannot physically go beyond, ensuring proper coaptation of it and its counterpart leaflet against its corresponding stop on the opposite side of the valve.

Referring now to Figure 14A through 14D, a still further embodiment of the present invention will be described. As seen in Figure 14A, sutures 60 may be secured to the tissues surrounding the heart valve at anchoring sites 88. The sutures may be secured in a variety of different methods including but not limited to passing sutures through the heart valve material to be looped through or knotted off using a knot pusher. The sutures  
20 may also be connected using anchoring devices as described in commonly assigned, copending U.S. Provisional Patent Application Ser. No. 60/388,250 (Attorney Docket No. 39308-0002) filed June 12, 2002.

As seen in Figure 14B, the sutures 60 may then act as guides to advance a slideable tissue supporting member 90 over the sutures to the tissues surrounding the  
25 heart valve. In one instance, the supporting member may be of similar size and shape to a conventional annuloplasty ring typically used to repair heart valves during open heart surgery. In one embodiment, the sutures 60 may be of sufficient length to extend from the attachment locations in the valve tissue to outside the body to allow for attachment to device 90. The device 90 may then be slidably advanced over the sutures to the target  
30 tissue. This advantageously allows for precise anchoring of the device 90 at the target site. As seen in Figure 14C, the device 90 may be have a single ring configuration that may be straightened or folded (in other embodiments) to be advanced through a guide catheter to the target site. Alternatively, the device 90 may be a continuous ring without a

break, but foldable to be advanced through the guide catheter. As seen in Figure 14D, a coil ring configuration device 92 may also be used, wherein both coils or rings of the device remain on the same side of the valve tissue. This may allow for additional attachment points on the device 92 or if the coils have varying diameters, different  
5 reshaping options based on different angles of the sutures to provide pulling or securing forces in different directions.

In the invention described, the ring may be advanced over the anchored sutures and advanced to the valve through a typical guide catheter. In such a manner, the entire procedure may be performed percutaneously, resulting in less trauma to the patient and  
10 providing improved valve function without the need for open heart surgery. After the ring is in position on the valve tissues, each of the locations where the sutures pass through the ring are fastened to the ring using the techniques previously described with clamps and/or knots. Alternatively, it may be possible to secure all of the sutures with a single clamp securing each of the sutures together, as shown in Figure , below.

15 Referring now to Figures 15A and 15B, in another embodiment of this invention, the device 110 consists of two separate halves or clamp portions 112 and 114, each of which may provide support for the valve while maintaining a clamping force between them. Clamp portion 112 may have an annular support 113 or leaflet that supports the tissue. Clamp portion 114 may similarly have an annular support 115 or leaflet that  
20 supports the tissue. The two clamp portions 112 and 114 are connected to each other via a central adjustable fitting. In one embodiment, the central fitting consists of a barbed connector or spine 116 on one device part that mates to a matching insert 117 on the opposite part with a lumen 118.

As seen in Figure 16, the center spine 116 could be split, having a slot 119, to  
25 permit the outer diameter of the spine to be adjustable, allowing the distance between the two parts to be adjusted by the physician *in-vivo*, until the improved function of the heart valve has been observed.

In a further preferred embodiment seen in Figure 17, the distal end 120 of the center spine 116 may incorporate holes 122 on each half of the barbs. Through the holes  
30 122 is a releasable suture or thread 60 that, when tension is applied, compresses the two halves of the spine 116 together, effectively decreasing its overall outer diameter. This permits the upper half of the device to be adjusted prior to release to allow for more distance between the two halves of the device and less clamping force on the valve area.

The complete assembly, including the releasable suture, is illustrated in Figure 18 (for illustrative purposes, the ring and clamp are shown as simple circular structures). In this manner, the clamping force on the valve and annular support device is entirely controlled by the physician prior to its release in the heart.

5           In a further embodiment of the present invention as seen in Figure 19, the device 110 comprises a lumen 130 through the center spine 116. The lumen 130 provides a space through which a slideable and removable guide wire may be inserted for placement of the device. A matching lumen on the mating half 118 of the device ensures that both pieces remain in the same axis when being delivered. Since both parts of the connector  
10           are maintained in axial alignment, securing the devices together is accomplished by pushing the two devices together.

          A pushing device 134 of Figure 20, consisting of a tubular member, allows for tension to be placed on the releasable suture 60 without disrupting the location of the valve support device by holding the center spine in position while tension is applied to the  
15           suture. After the desired improvement in valve function has been obtained, the suture is removed by simply releasing one end of the suture and pulling on the other end until the entire suture has been removed from the body. Additionally, other release mechanisms include clamping jaws, screw threads, and other mechanical means, that are releasably connected to the support structure in order to maintain control over the device and to  
20           remove the structure from the body if improvement is not realized or for any other reason.

          Again, each of the halves 112 and 114 of the device may be hollow allowing for them to be straightened over a mandrel or guide wire for delivery into the valve area. Upon delivery to the valve area, the device(s) are advanced off the removable mandrel/guide wire and they revert back to their pre-determined shape.

25           In addition to the various coil type annular support rings described above, other types of annuloplasty device may also be used in accordance to the present invention.

          Referring now to Figures 21 and 22, in another embodiment of the present invention, a valve support structure 210 is delivered to the valve area via a guide catheter. The device 210 comprises of a central body 212, a first leaflet clamp 214 defining an  
30           upper compressive portion, and a second leaflet clamp 216 defining a lower compressive portion. The clamp 212 and clamp 214 may be positioned to engage the valve leaflet therebetween.

Referring now to Figure 23, the number of leaflet clamp sets on the device may match the number of leaflets of the valve. For instance, the mitral valve device of this invention may have two sets of clamps. The tricuspid device design may, but is not required to have, three sets of leaflet clamps 220 as seen in Figure 23. In either instance, the clamps are connected at a central location and radiate outwards towards the valve leaflets.

Each leaflet clamp 220 may have a different geometry, depending on the condition of the valve. For instance, if more support is desired at the outer edge of the leaflet, the clamp could have a larger diameter in that area. Figure 24 shows a wire loop leaflet clamp 220 having a curved configuration where the wire extends radially outward and then returns to the central body 212. Figure 25 shows an embodiment where the change in width is more pronounced as the wire loop reaches the outer radial portion of the clamp. Figure 26 shows an embodiment having an oar or paddle configuration. It should be understood that a variety of different geometries may be used to support the leaflet clamps.

Referring now to Figures 27A-27C, the cross section of the clamp 220 may also have various geometries. For instance, it may be desirable to distribute the clamping force over a larger area, in which case a flattened cross section would be appropriate as seen in Figure 27B. Alternatively, rounded cross sections may be used in areas where there may need to be increased force on the tissue surface as seen in Figure 27C.

It can be appreciated that there may be any number of configurations for the clamps 214 and 216. For instance, if most of the support for the valve is needed at the area of the annular ring, the clamps may not provide any clamping force on the leaflets themselves, but would be of sufficient overall diameter and distance away from the central hub so as to provide support in the annular area of the valve. Conversely, if a percutaneous procedure yielding similar results to the "bow-tie" procedure is desired, the clamps may be of relatively small outer diameter. In this manner, only the leaflets would be clamped together more central to the device, effectively decreasing the movement of the leaflets, and providing a forced coaptation. Additionally, as seen in Figure 27D, a combination of both annular support 222 and leaflet coaptation 224 could be achieved in the same device by providing multiple clamps of different diameters to support both the valve leaflets and the valve's annulus.



Referring now to Figures 28-30, delivery of the device 210 may be achieved through a guide catheter 230. Each of the leaflet clamps 214 and 216 may be made of a superelastic material such as, but not limited to, Nitinol, such that the leaflet clamps 214 and 216 can be folded up into the guide catheter to assume a folded configuration. As  
5 seen in Figure 28, the leaflets clamps are deflected towards a longitudinal axis 231 of the central body to provide a reduced diameter 232 so that the device 210 will fit inside the guide catheter but still assume an expanded configuration with an extended diameter upon exiting the catheter.

As seen in Figures 29 and 30, upon release across the heart valve V, the leaflet  
10 clamps 214 and 216 return to their functioning state with the extended diameter 234. Alternatively, the device 210 may be made of any one of a number of shape memory alloys, allowing it to be delivered in a straight configuration through the guide catheter, and re-assuming its functioning form following the application of energy in the form of electrical, radio frequency, microwave, and such. In any case, the guide catheter is  
15 traversed across the target valve. At the desired location, the device is pushed out the distal end of the guide catheter and upon exiting the guide catheter as seen in Figure 29, the distal leaflet clamp 214 assumes its clamping dimensions.

The guide catheter 230, still with the proximal leaflet clamps 216 inside in their folded configuration, is then retracted proximally across the valve opening where the  
20 remainder of the device 210 is delivered. The leaflet clamp 216 then extends to their preformed configuration with diameter 234, engaging or urging the valve leaflet against the opposing clamp 214 as seen in Figure 30.

Referring now to Figures 31-35, there are several ways the mitral valve can be accessed percutaneously to deliver the devices described herein, although it should be  
25 understood that the devices may be used during open heart surgery as well. As seen in Figure 31, one route utilizes the femoral artery approach where the guide catheter 250 is threaded through the femoral artery in the groin and advanced retrograde against the flow of blood, over the aortic arch, through the aortic valve, into the left ventricle of the heart, and directed towards the mitral valve.

Referring now to Figure 32, a second approach that may be used during  
30 percutaneous valvuloplasty procedures involves the venous approach to the heart. The guide catheter 252 is advanced through the vena cava into the right atrium of the heart and is directed across the atrial septum of the heart into the left atrium of the heart. This

approach has been demonstrated to be well-tolerated by the body with few adverse events.

Referring now to Figure 33, a further method for device placement is described herein that provides unique advantages for devices attempting to modify the performance of the mitral valve percutaneously. First, a trans-septal guide catheter is advanced through the atrial septum of the heart to the superior side of the mitral valve. An extra long guide wire 254, is then advanced through the guide catheter 252 and into the left ventricle. A second guide catheter 250 is advanced to the left ventricle of the heart via the arterial approach. A snare (not shown) may then be advanced through the arterial guide catheter 250 and captures the distal end of the trans-septal guide wire 254. The snare is retracted through the arterial guide catheter 250 where the distal end of the guide wire is captured and secured outside the body. In effect as shown in Figure 34, the guide wire 254 provides a passage from either or both directions, arterial or venous, to the mitral valve of the heart.

Referring now to Figure 35, a support ring 114 when threaded over the guide wire from the arterial side need not even cross the mitral valve to provide support to the ventricular side of the valve. Similarly, a second support ring 112 forming device 110 when combined with ring 114, intended to provide support to the atrial side of the mitral valve also need not cross the valve when delivered via the trans-septal route. In this manner, the two halves of mitral valve device 110 can be delivered through the two guide catheters and meet up at the mitral valve. The guide wire 254 additionally ensures that the two mating parts of the device remain in axial alignment when assembled across the valve.

Referring now to Figure 36, the device 10 or any of the other devices 110 or 210 as described herein, may be included in a kit 300 contained in a pouch or container 302. Instructions for use IFU are also contained in or attached to the container 302. The instructions provide a method for using device 10, a method for attaching device 10 to tissue, or instructions on how to deliver device 10 or similar device using a delivery device 20 such as a catheter or straightening mandrel that may also be contained in container 302. It should be understood that the kit 300 may include anchors and delivery devices 500 in addition to or in place of devices 110 and 210.

Figure 37 shows that sutures or threads may be removed from the angioplasty ring.

Referring now to Figures 38 and 39, it can be appreciated that the cross section of the guide wire 310 may be shaped to ensure the proper orientation of the two device halves. In this manner, torqueing of the guide wire 310 with the device 312 slideably attached also orients the device 312 loaded on the guide wire. The steerability of the guide wire 310 and the valve device may help in the proper orientation of the clamps 314 of the device onto the leaflets of the valve.

Referring now to Figure 40, additionally in a still further embodiment, an integral bump 320 on the guide wire 322 may aid in providing additional force to connect the valve support device or to seat it against the tissues of the heart valve. The bump 320 on the guide wire 322 provides enough interference with the device so that as the guide wire is advanced or retracted, it pulls the device along with it.

Referring now to Figure 41, additional placement techniques for the device according to the present invention include using thoroscopic techniques to place the devices. During this procedure, a small port(s) is usually used to access the heart tissues. The port is typically paced between the ribs using laparoscopic methods. A metallic tube or guide catheter is then advanced up to the heart tissues to gain access to the major vessels and the exterior of the heart muscle. The technique that may be particularly useful is where the anchor is inserted through the heart muscle at or near the level of the damaged valve.

The hypo delivery tube 330 pierces through the heart muscle into the atrium or the ventricle near the valve. The needle is then further advanced across the interior of the heart to the opposite side of the valve where it again pierces through the heart wall. The anchor 332 is then deposited on or in the opposite side of the heart and the suture 334 left behind in the path of the needle as the hypo is retracted from the heart muscle as seen in Figure 42.

A clamp 336 may then be advanced down the suture to the initial side of the piercing. As the clamp 336 is further advanced, the sides of the heart are drawn closer to each other, assisting the valve leaflets in proper coaptation and improved function.

It should be understood that although a suture is described, a steel rod or similar support structure may be used to transverse through the heart muscle. The main concept is that opposite sides of the valve are brought closer to one another by an external force on the heart muscle. Alternatively, if valvular stenosis is being treated, the valve can be

forced open in a similar manner. In this manner, the spanning structure is rigid since it is under compression from the force of the heart muscle on the spanning rod.

Yet another embodiment of the present invention comprises the ventricular half of the annular support device having struts 340 instead of a ring or clip-like structure. The struts 340 are designed to atraumatically navigate through the chordae tendonae in the ventricle of the heart. During advancement through the guide catheter 342, the legs are extended distally. Upon exiting from the guide catheter, the legs 340 begin to spread outwards from the tip of the guide catheter towards the circumference of the valve. During their advancement, the legs gently push aside the chordae, if any, in their pathway.

The ends of the legs or struts 340 may be shaped in any of a number of ways to allow for either more surface area on the ventricular side of the valve or to advance through the chordae easier. For instance as seen in Figure 45, small spherical bulbs 344 on the ends of the legs provide a smooth leading edge for the legs with little risk of snagging a chord as the legs advance through the chordae. After traversing through the chordae, the landing pads on the legs secure themselves on the ventricular side of the mitral valve, either at the leaflet or directly onto the annulus of the valve. In other embodiments, the ends of struts 340 may have a hockey feet 346 configuration or a zig-zag 348 configuration.

Referring now to Figure 46, another aspect of modifying the heart valve for improved function includes devices that treat valvular stenosis. These devices provide expansive forces to the valvular annulus in order to increase the open area of the valve through which blood flows. One such device 350 utilizes an outward expansive force to apply pressure to the annular area of the heart valve as indicated by arrows 352. The coil is delivered through a standard guide catheter and, upon exiting the distal end of the guide catheter, the device assumes a pre-determined generally ring-shaped structure that presses itself against the heart wall, either immediately superior (atrial side) or inferior (ventricular side) of the valve.

Alternatively, the device may be generally cylindrical in shape, and upon exiting the guide catheter, it assumes a larger diameter that presses against the heart wall, either immediately superior (atrial side) or inferior (ventricular side) of the valve. Furthermore, the device may be hollow, allowing for it to be straightened for delivery over a removeable straightening mandrel or guide wire. Upon removal of the mandrel or guide

wire, the ring reverts back to its larger diameter pre-determined shape and provides a force on the interior of the heart wall, thus modifying the function of the heart valve in its vicinity.

Referring now to Figure 47, another aspect of this invention provides devices,  
5 methods and systems for suturing and repairing tissues of the body. Specifically, tissues can be "cinched" together, or brought into closer proximity to one another, using the devices described herein. In one embodiment of this invention, anchors 360 are attached to the tissues to be cinched. Attached to the anchors 360 are sutures 362. A slideable clamp is attached to the sutures. As the clamp 364 is slid closer to the anchor points, the  
10 tissues are brought closer together. When the desired position of the tissues has been achieved, the clamp 364 is set in position and the excess suture material from each anchor point is severed and removed.

The anchors 360 may be of any of a number of configurations. For instance as seen in Figure 48, a spear-like design would enable the anchor to penetrate tissue with the  
15 barb providing adequate resistance to the tension applied to the suture during the cinching process.

Referring now to Figure 49, in the case of repairing a heart valve, two or more anchor 360 may be placed in any of the tissues surrounding the valve leaflets, including the leaflets themselves. Following the proper placement of the anchors and attached  
20 sutures 362, the slideable clamp 364 is advanced over the sutures and adjusted to provide adequate tension on the anchor points on the valve to provide improved coaptation of the valve leaflets. When adequate improvement in the function of the valve has been obtained and verified, the clamp is set in place and the excess suture material cut and removed.

25 For illustrative purposes, the clamp 364 is shown as a tubular member, however, simple means of securing the tension on the sutures may be accomplished by any one of several means. For instance as seen in Figure 50, a simple knot 366 tied in the proximal end of the sutures and advanced towards the valve by a knot pusher, would provide adequate means for securing the tension in the sutures.

30 Referring now to Figure 51, in another embodiment, one or more anchors 360 and sutures 362 are secured to the tissues surrounding the heart valve. The sutures then act as guides to advance a slideable tissue supporting member 370 over the sutures 362 to the tissues surrounding the heart valve. In one instance, the supporting member 370 may be

of similar size and shape to a conventional annuloplasty ring used to repair heart valves during open heart surgery.

In the invention described, the support member 370 may be advanced over the anchored sutures and advanced to the valve through a typical guide catheter. In such a manner, the entire procedure may be performed percutaneously, resulting in less trauma to the patient and providing improved valve function without the need for open heart surgery. After the support member 370 is in position on the valve tissues, each of the locations where the sutures pass through the ring are fastened to the ring using the techniques previously described with clamps and/or knots. Alternatively, it may be possible to secure all of the sutures with a single clamp 372 securing each of the sutures together, as shown in Figure 52.

In one embodiment, the support member material may be made porous in order to promote endothelialization of the member 370 around the valve. A more secure device may aid in the support the implantable ring provides to the valve tissues. Suitable materials for the ring include nitinol, ceramics, and plastic polymers. Additionally the materials used may elude drugs that may assist in the promotion of endothelialization. Alternatively, the support member 370 may be surrounded by materials such as polyester that promotes tissue ingrowth and endothelialization of the device.

Referring now to Figure 53, in another aspect of this invention, the anchors 360 incorporate a loop 376 of material or a lumen through which a suture may slide 380. The first anchor 360 placed typically has a non-slideable suture attached. Once the first anchor point has been secured in the desired location, subsequent anchors 378 are slid over the primary suture and secured to the tissues of the valve.

As tension is applied to the primary suture 380, each of the anchor points are brought into closer proximity to one another (see Figure 57), resulting in improved coaptation of the valve leaflets and improvement in the function of the heart valve. Following the final anchor attachment to the tissues, a single clamp 372 or knot is advanced to the location of the final anchor and secured in place following verification of improved function. Valve function may be verified by any one of many suitable means including, but not limited to, echocardiography, angiography, magnetic resonance imaging, etc.

Referring now to Figure 54, the anchors may be of any suitable design to provide adequate prevention of dislodgement when the primary suture is place in tension. An

alternative embodiment to the barbed spear is a "T" bar design anchor 382 is used in various alternative procedures such as in gastrostomy placement.

Referring now to Figure 54, in one embodiment, the "T" bar 382 is placed via a hypodermic needle or tube 384. The needle 384 punctures through the tissues to be  
5 cinched and then the "T" bar 382 is deposited on the opposite side by a simple mandrel or "T" bar pusher. The needle is then retracted leaving the "T" bar anchor securely fastened to the opposite side of the tissue as seen in Figure 56.

Subsequent anchors are added by removing the "T" bar pusher from the catheter, loading a slideable anchor over the primary suture, and advancing the anchor through the  
10 hypo tube to the next desired position. The target tissue is then pierced by the "T" bar delivery hypo tube, the "T" bar anchor pushed out the end of the hypo, and the hypo retracted, leaving the "T" and primary suture attached to the anchor point. Additional anchors may be placed in a similar fashion as seen in Figure 57.

Referring now to Figure 58, in this manner, multiple anchor points 388 may be  
15 placed around a heart valve or other tissue that is in need of support. As tension is applied to the primary suture, the anchors provide the points at which constriction occurs and the overall diameter of the valve annulus is reduced much like the use of a belt through the belt loops on a typical pair of trousers. By this method, several series of anchors and sutures may be placed that specifically provides constriction on only those  
20 areas of the valve that may be in need of cinching.

It is important to note that although the repair of the heart valve is described, this device and technique may also be very useful in the non-surgical repair of other tissues within the body. For instance, Gastrointestinal Reflux Disease may be treated by using these techniques on the sphincter between the esophagus and the stomach. By effectively  
25 decreasing the overall diameter of the excess opening typical of this disease, normal function may be restored. Additionally, urinary incontinence may be treated using similar techniques and devices on the sphincter between the bladder and the urethra. In these instances and others, surgery may be significantly reduced or eliminated, thus sparing the patient from the risks of surgery and the necessary recovery from such trauma.

Referring now to Figure 59, another technique that can be used is where each of  
30 the anchors 390 are slidable with no primary anchor. Instead of the initial anchor having a permanent suture attached, a single (or multiple strands) suture 392 is threaded through a hoop on each of the anchors 390 with both ends of the suture exiting through the

delivery guide catheter. The tissue is then cinched together by advancing a knot or clamping device 364 using the two ends of the suture as the point where the tension is applied.

Referring now to Figure 60, if a clamp 364 is advanced towards the anchors, the clamp itself may have a means to both clamp the ends of the suture together and simultaneously cut the excess suture material from the site. Figure 60 shows a clamp 400 with a crimping area 402 and a cutting area 404.

Another method is where each of the anchors has non-slidable sutures permanently attached. In this instance, all of the ends of the sutures can be pulled together, and tied or clamped with a single knot or clamping device.

Referring now to Figure 61, the hypodermic delivery tubing 410 for the "T" bar anchors or similar anchors may be of any number of suitable configurations to deliver the anchors. In one embodiment, the tubing 410 employs a simple sharpened needle tip 412 to puncture through the valve, leaflets, and/or the heart tissues surrounding the valve. The application of forward pressure on the tubing provides sufficient force for the tubing 410 to pierce the tissues and deliver the anchor to the opposite side of the heart structure.

Referring now to Figure 62, in another embodiment, the tubing 414 has a sharpened inner removable piercing obturator 416 that punctures through the heart tissues. After the tubing is through the tissues, the obturator is removed, allowing the anchor to be passed through the hypo tubing to the heart tissues.

Referring now to Figure 63, in another embodiment, the obturator tip 418 has self-tapping threads 420 on its distal end. Torqueing of the obturator screws the delivery hypo into the heart tissues. After the hypo 414 has been delivered to the desired location, the obturator is removed, allowing the anchor to be passed through the hypo tubing.

Referring now to Figure 64, in another embodiment, the hypo tube 422 has threads 424 on its surface to permit the engagement of the hypo tube 422 with very little force. Torqueing of the hypo tube 422 screws the tubing into the heart tissues without requiring additional forward force on the tubing. In some cases, it does not require forward force greater than that used with a sharpened hypo tube. Once through the tissue, anchors may be advanced through the hypo 422 to their desired position.

Referring now to Figure 65, another embodiment utilizes self-tapping threads 420 on both the inner cannula 426 and the outer delivery hypo tube 428, preventing the possibility for coring of the tissue with the hypo tubing alone.



Referring now to Figure 66, in yet another embodiment, the anchor 430 itself employs self-tapping threads 420 to engage the tissue and advance itself to the opposite side of the targeted tissue.

Referring now to Figure 67, alternatively, the anchor 432 may be a simple self-tapping thread or a helix of sharpened wire similar to the distal tip on an active-fixation  
5 pacemaker lead that is secured to the heart tissue by torqueing through the tissue.

Referring now to Figure 68, one possible improvement on the helical anchor 434 is that the helix may be of variable radii. For instance, the initial distal engaging winds of the helix may be of relatively small diameter, increasing in diameter proximally.

Referring now to Figure 69, in this instance, additional anchoring force is provided, allowing for a more secure attachment. Additionally, the suture material 440 may be attached to the distal end 442 of the helix such that as more force is applied to the anchor by the suture, the anchor 444 tends to collapse upon itself, further providing additional support to the tissues in which it is attached.

Referring now to Figure 70, delivery of the anchor 432 is accomplished by securing the anchor 432 to a releasable delivery shaft 446. In one method of delivery, the anchor 432 is secured to the heart tissue by clockwise motion. Engaging threads 448 on the delivery shaft 446 allows clockwise rotation of the anchor for securement. Counterclockwise rotation of the delivery shaft 446 disengages the anchor 432 from the  
20 threads 448 on the delivery shaft. The delivery shaft is then removed from the guide catheter, leaving the anchor firmly secured within the heart tissue.

Referring now to Figure 72, in another embodiment, the distal end of the guide catheter 450 releasably locks or engages at least a portion of the anchor 432. The anchor 432 is delivered with the engaging portion of the guide catheter retracted, and following  
25 delivery of the anchor, the guide is then advanced up to the anchor point to engage a portion of the anchor. By rotating the delivery shaft 450, the anchor is held in place, while the delivery shaft disengages. The guide catheter is then retracted from the anchor, leaving the anchor secured to the tissue.

Referring now to Figure 72, another method of delivery for the anchors is the simultaneous deployment of multiple anchors 460 at a time. In this manner, the delivery  
30 shafts 462 for two or more anchors are deployed at a variable distance apart. For instance, the ends of the delivery shafts 462 may be pre-shaped into a curved geometry

such that as they exit the guide catheter, they progressively move further apart from each other.

Referring now to Figure 73, the more the delivery shafts 462 are advanced out the guide catheter, the greater the distance between the anchors 460. In this manner, several  
5 anchors 460 can be delivered in a pre-determined configuration at a pre-determined diameter away from the guide catheter. This eliminates the need to individually place each anchor at a desired location. Each projection outward from the guide catheter tip need not contain an anchor. In other words, one or more additional projections 464 may be used to center the device within the lumen of an artery or within the valvular tissue  
10 such that the anchors being delivered are oriented in the desired directions.

The anchor(s) may be porous in order to promote the endothelialization or encapsulation of the anchor in the tissue to obtain a more secure, long-term hold in the valve tissue. Suitable materials include ceramics, nitinol, elgiloy, stainless steel and the like. Alternatively, various polymers may be used that may or may not elude drugs to  
15 further promote endothelialization of the heart tissues into and around the anchors and/or the various other devices and inventions described herein. Additionally, the device may be used to close tubular organs, punctures or vessels from inside the tissues. In one instance, the fallopian tubes of a woman may be closed for permanent birth control. The device is threaded through a fallopian tube access catheter trans-cervically to the interior  
20 of the fallopian tube. One or more anchors may be delivered through the wall of the fallopian tube from the inside. The anchors are then secured to the exterior of the tubal wall and cinched together to close the tube. A clamp or knot that provides closure force is advanced to the site and secures the individual suture leads together. Again, the sutures may be fibered, stranded or bundled in order to facilitate tissue ingrowth and a more  
25 permanent occlusion of the fallopian tube. In this same fashion other organs, tissues and body passageways may be closed from the inside in order to effect the desired therapy or treatment.

Referring now to Figure 74, another aspect to the delivery of the anchors is in providing a means for the guide catheter to grip or hold the tissues in close proximity to  
30 the distal end of the guide catheter. One such means is the provision for a simple vacuum to be placed on the proximal end of the lumen of the guide catheter 470. As the tip of the guide comes close to a soft tissue, the tissues are sucked closer to the guide catheter tip and held in place by the suction.

This vacuum device, the guide catheter 470 with an attached or detachable vacuum source, may also be particularly useful in the fixation of the stomach wall prior to percutaneous gastrostomy placement.

Referring now to Figure 75, it is important to note that the anchors 460 may  
5 provide a means to improve the function of the heart valve alone, they may also be used to provide an anchoring means for various other devices used in the interventional treatment of cardiovascular diseases. For instance, although providing a means to secure the percutaneous annuloplasty rings described earlier, they may also be used to secure or affix a stent 480, or stent-graft to a vessel wall. In this application, first the anchors are  
10 delivered and secured to the desired tissue, such as the abdominal aortic vessel wall. The sutures on the anchors are threaded through loops such that the stent device can slide over the sutures. The stent is then advanced to the anchoring site. Knots or clamps are then advanced up to the stent so that the stent is then secured to the vessel wall at each of the anchor points.

15 Alternatively, the anchors may be added after the stent has been delivered. The stent has specific points of attachment through which the anchors are delivered into the vessel wall. In this manner, the need for any suture material is completely avoided as seen in Figure 76.

Referring now to Figure 77, another aspect of this invention is an artificial valve  
20 490 to replace a destroyed natural valve within the body. The natural valve may be one of the heart such as the mitral or aortic valves. Alternatively, the valve may be used in the legs of a patient with venous insufficiency. By providing improved fluid dynamics over the patient's natural valve(s), pooling of blood in the legs, typical in this disease, is minimized. The valve device 490 includes the valve itself, as well as an outer expandable  
25 support structure that secures the valve within a desired segment of blood vessel. The valve 490 may be made from materials typical of cardiac valves, such as carbon, silicone, nitinol and the like. Alternatively, the valve of this invention may be a tissue valve from a donor host, similar to porcine or bovine valves used for cardiac valve replacement. The valve may be processed venous valves from these animals, or they may be made from a  
30 valve structure that is temporarily grown within the living tissues of a host animal.

Yet another aspect of this invention provides a means for repairing the chordae tendonae that connect the leaflets of the mitral valve to the ventricular wall. In this device, the anchor is directed through the leaflet of the valve from the atrial side of the

heart and placed within the ventricular wall. The leaflet is held in place by a knot or a clamp secured to the atrial side of the leaflet onto the suture attached to the anchor.. Several sutures may be place in each of the leaflets in order to prevent prolapse during systole of the heart.

5 Referring now to Figure 78, a still further embodiment of a tube 500 for engagement of the tube 500 into tissue with reduced forward force. Torqueing of the tube 500 screws the tubing into the tissues through the cutting action of the helically cut distal portion 502 of the tube 500. Although not limited to the following, the cutting distal portion 502 may be formed by laser cutting or otherwise cutting a tube to remove material  
10 and form the structure shown. Other patterns may also be cut in the tube so long as they permit the tube to be advanced into tissue via torquing of the tube 500. Once through the tissue, anchors 504 may be advanced through the tube 500 to their desired position. In some embodiments, a pusher 506 may be used. In some embodiments, the anchor 504 may have a diameter substantially similar to that of the inner diameter of the tube 500 but  
15 allowing for unimpeded delivery of the anchor through the tube. A suture 506 may be coupled to the anchor 504.

Referring now to Figure 79, one embodiment of the tube 500 or elongate delivery device is shown penetrating through tissue T and delivering the anchor 504. Arrow 510 indicates that rotation of the delivery device 500 will cause the distal end 502 of the  
20 device 500 to engage tissue and draw the entire device 500 into and through the tissue. In some embodiments, anchor 504 may have a sharpened tip as indicated by dotted line 512 to allow the anchor 504 to be driven through the tissue.

Referring now to Figure 80, in this embodiment, a guide catheter 520 may be used to guide the elongate delivery device 500 into the correct location for penetration into  
25 tissue T. It should be understood that the tube or device 500 may have any of the distal tips disclosed herein and may be used with any combination of anchors disclosed herein. The tube 500 may be rotated within the guide catheter 520 to enable the front end of the tube 500 to engage tissue. In other embodiments, the tube 500 is simply pushed forward to pierce the tissue T.

30 Referring now to Figures 81 and 82, the support member 530 after being delivered to a target site, may use a suture 532 to tighten the tissue coupled to the support member 530. The member 530 may be secured by anchors or sutures as described in regards to Figures 14A-14C and Figure 51.

Referring now to Figures 83 and 84, the anchors 504 may be delivered through tissue using a delivery device 500 or the like to send an anchor 504 through tissue T. This technique may be useful in patent foramen ovale (PFO) closure in heart tissue. As seen, a suture 540 with anchors 504 may be used for tissue connection.

5 Referring now to Figures 85 and 86, a still further embodiment of an anchor 550 is shown. The anchor 550 has outward extending member 552 or barbs which will secure the anchor in tissue after delivery from the catheter 500. This may be useful in situations where the anchor 550 does not fully penetrate through tissue and may rely on the barbs for anchoring force.

10 While the invention has been described and illustrated with reference to certain particular embodiments thereof, those skilled in the art will appreciate that various adaptations, changes, modifications, substitutions, deletions, or additions of procedures and protocols may be made without departing from the spirit and scope of the invention. For example, the geometric configuration of the loops of device 10 or 210 may be varied  
15 as desired to provide leaflet support, including shapes such as square, triangular, bowed, rounded, or other configuration. The wire loop elements may also be replaced by solid elements, such as a solid, oar shaped clamp instead of a wire loop. Although device 10 is generally shown to have a circular relaxed configuration, it should also be understood that, in all embodiments, the device may have a square, rectangular, triangular, polygonal,  
20 or other shape that will provide suitable reduction of valve regurgitation. Additionally, bringing together tissues in closer proximity to one another is one method for closing wounds such as catheter puncture sites during percutaneous procedures (angioplasty, stenting, endograft procedures and the like), as well as in stomach stapling for the morbidly obese, gastrostomy placement, etc. These procedures all may benefit from the  
25 inventions described herein. Additionally, any of the inventions and devices described in this application may be manufactured, at least in part, using animal, human or cultured cells and tissues incorporated in whole or in part. These tissues may be harvested or cultured through tissue engineering or altered by the manipulation of their genetic content. In such a manner, these devices may be incorporated into the target location easier, may  
30 be less prone to rejection by the body, or may elude certain chemicals and/or enzymes that may be beneficial to the targeted tissues or the body as a whole.

Expected variations or differences in the results are contemplated in accordance with the objects and practices of the present invention. It is intended, therefore, that the

invention be defined by the scope of the claims which follow and that such claims be interpreted as broadly as is reasonable.

WHAT IS CLAIMED IS:

1. A tissue connecting device, the device comprising:  
an elongate delivery device having a lumen, a proximal end, and a distal end;  
wherein said distal end is configured to engage tissue and advance said device into tissue;  
at least one anchor deliverable through a lumen of said elongate delivery device.
2. The device of claim 1 wherein said delivery device pierces tissue through rotation of the delivery device about a longitudinal axis;.
3. The device of claim 1 further an elongate member deliverable to the target site via a guide catheter, said elongate member assuming a first substantially linear configuration while engaged with said guide catheter and a second substantially circular configuration defining a first support ring and a second support ring when removed from the guide catheter.
4. The device of claim 2 wherein said elongate member is slidable delivered along at least one suture coupled to said anchor.
5. The device of claim 1 wherein a helical configuration is laser cut at the distal end of the delivery device.
6. The device of claim 1 wherein threads are formed on the distal end of the delivery device and adapted to engage tissue.
7. The device of claim 1 wherein said at least one anchor has threads and are adapted to engage tissue.
8. The device of claim 1 wherein said at least one anchor has a helical configuration.
9. The device of claim 1 wherein said at least one anchor has a suture coupled to a distal end of the anchor.

10. The device of claim 1 further comprising a plurality of anchors wherein each anchor is coupled together by a suture.

11. The device of claim 1 further comprising a plurality of anchors wherein each anchor is coupled together by a suture.

12. The device of claim 1 wherein said anchor has a shape selected from one of the following: screw, a helix, a helix with variable radii, a bar, a hollow elongate portion or coiled shape.

13. The device of claim 1 wherein said anchor includes an eyelet for an anchor.

14. The device of claim 1 wherein said anchor includes means for attaching into tissue.

15. A system for tissue connection comprising:  
an elongate delivery device having a lumen, a proximal end, and a distal end;

wherein said distal end is configured to engage tissue and advance said device into tissue through rotation of the delivery device about a longitudinal axis;

means for anchoring tissue deliverable through said delivery device;

an elongate member deliverable to the target site via a guide catheter, said elongate member assuming a first substantially linear configuration while engaged with said guide catheter and a second substantially circular configuration defining a first support ring and a second support ring when removed from the guide catheter.

16. A system for tissue connection comprising:  
a plurality of tissue anchors coupled to a single suture, wherein said suture is slidably coupled to each anchor, wherein the anchors are configured so that tissue coupled to each of said anchors will be draw together when the suture is tightened.



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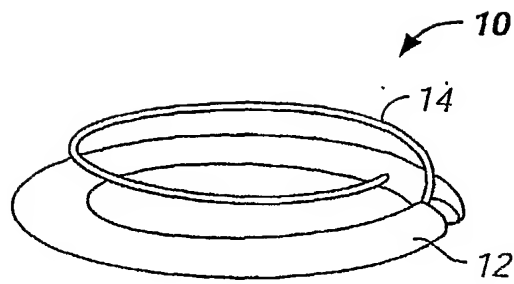


FIG. 1

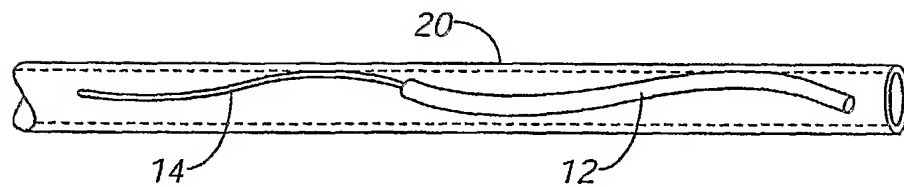


FIG. 2

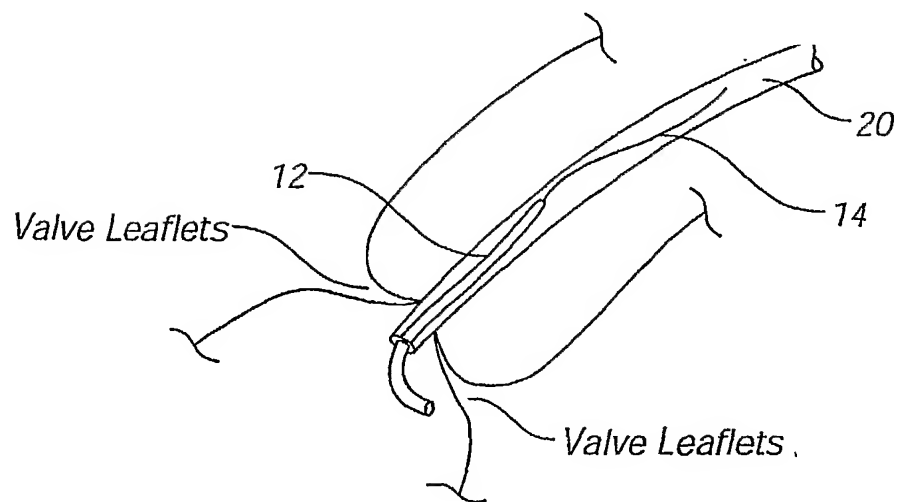


FIG. 3

2/30

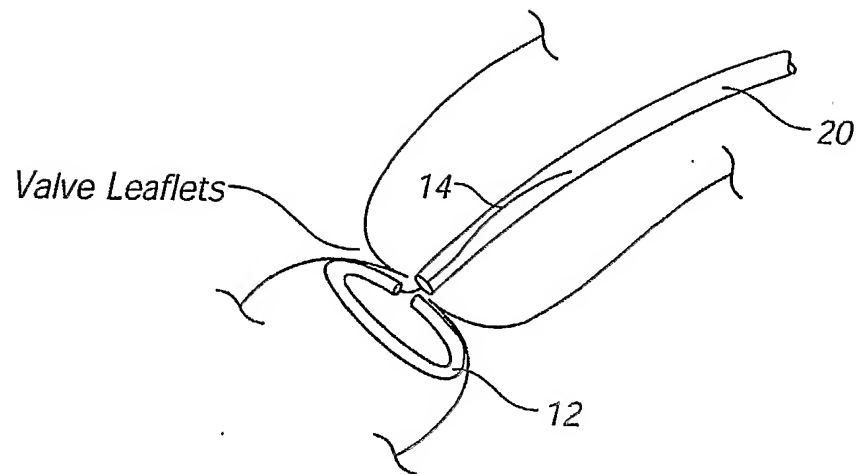


FIG. 4

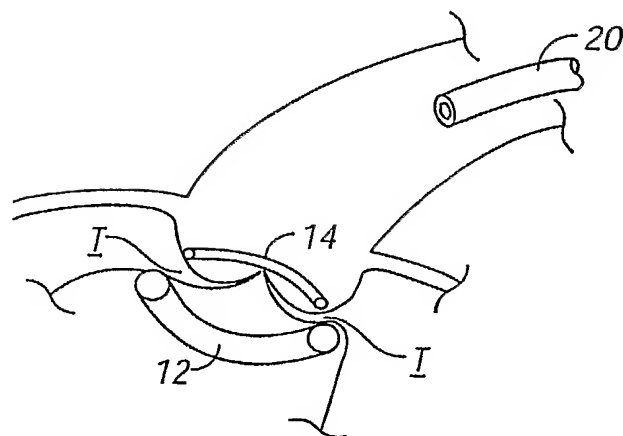


FIG. 5

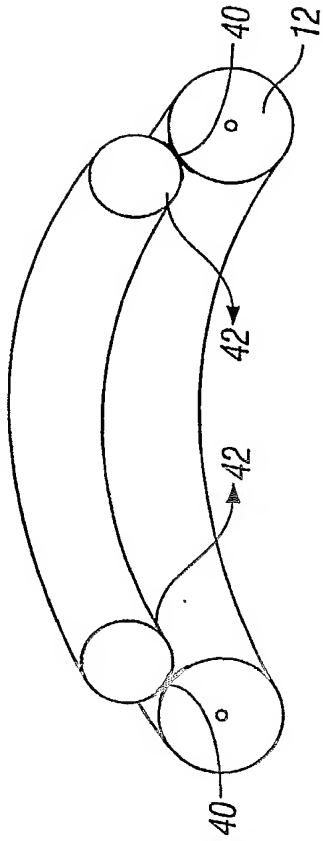


FIG. 7A

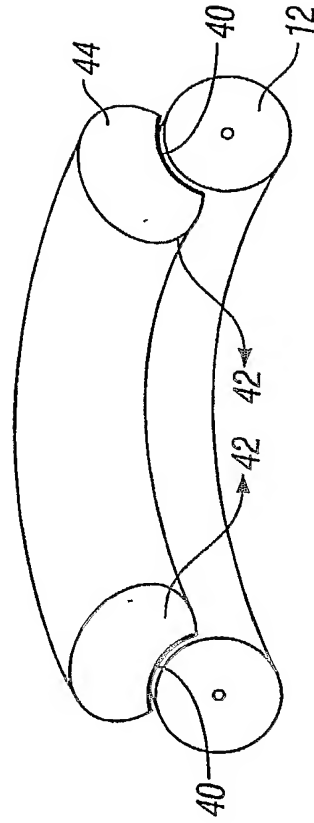


FIG. 7B

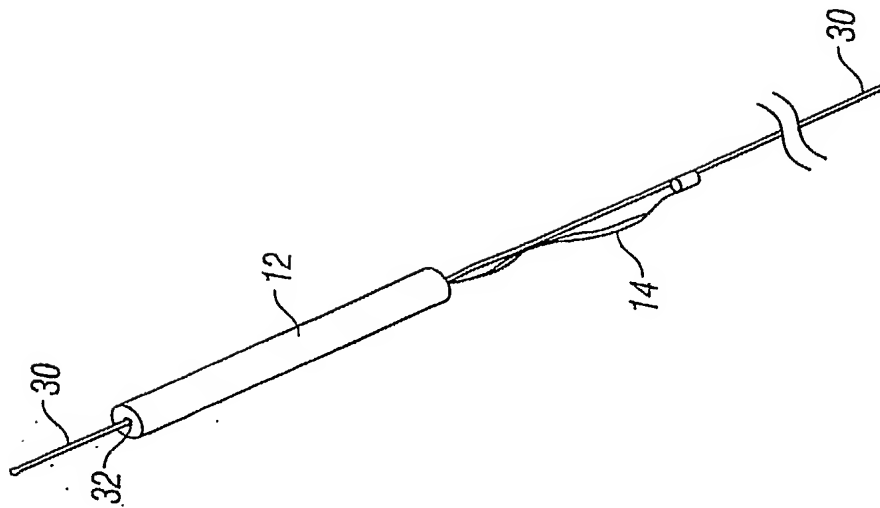


FIG. 6

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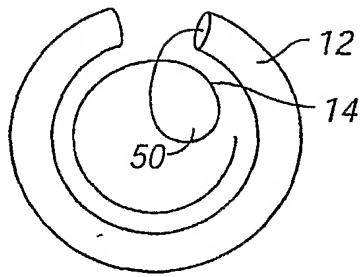


FIG. 8A

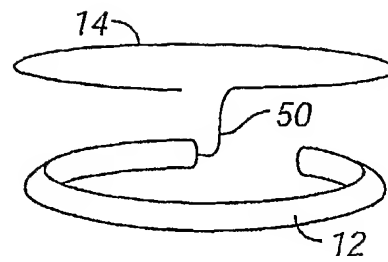


FIG. 8B

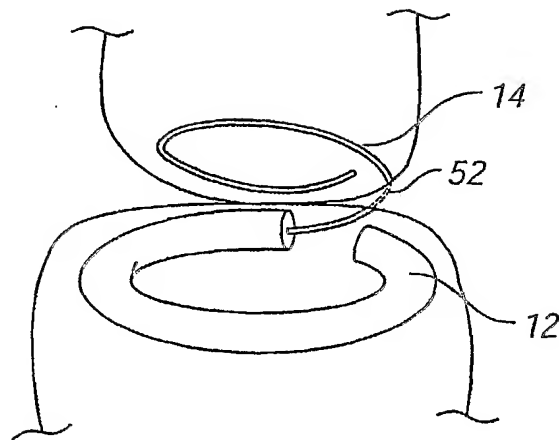


FIG. 9

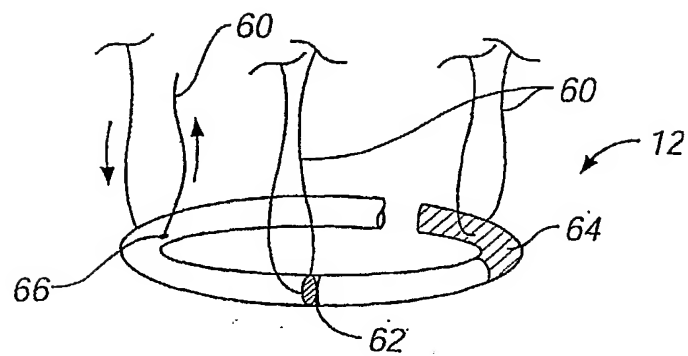


FIG. 10A

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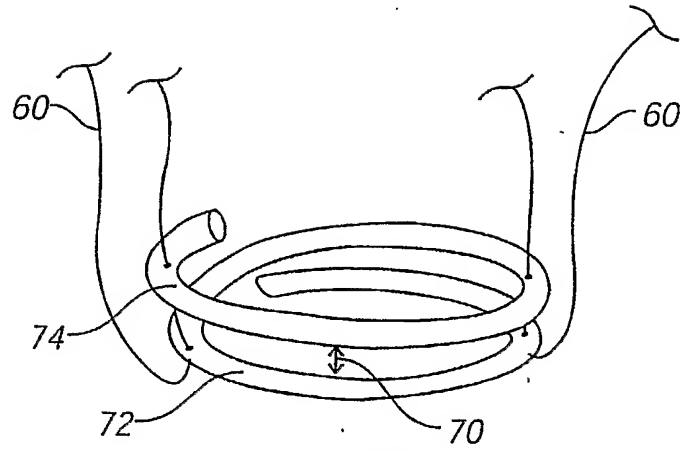


FIG. 10B

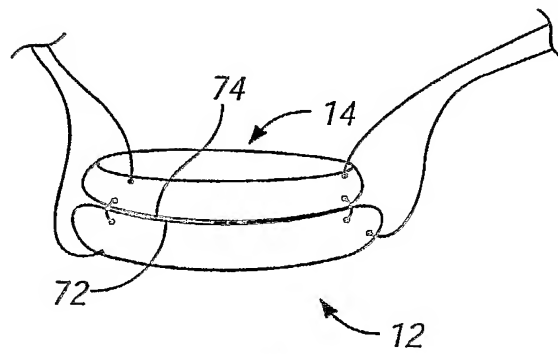


FIG. 10C

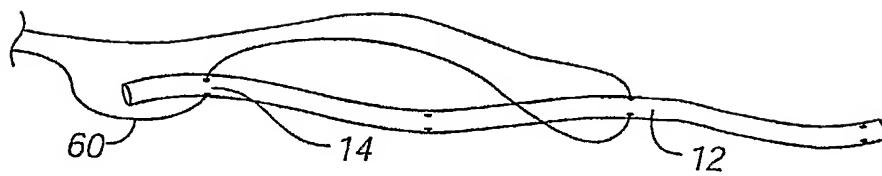


FIG. 11

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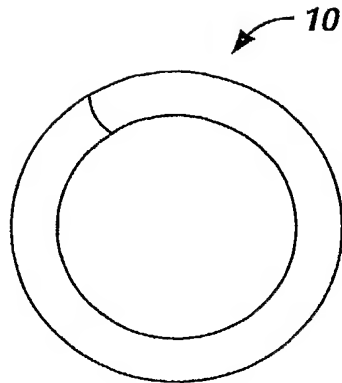


FIG. 12

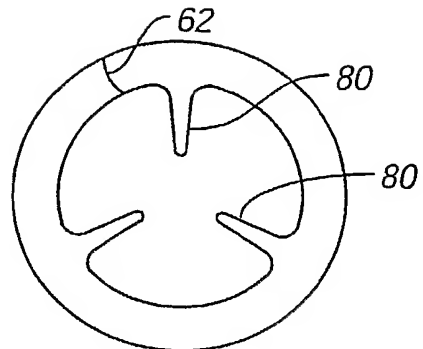


FIG. 13A

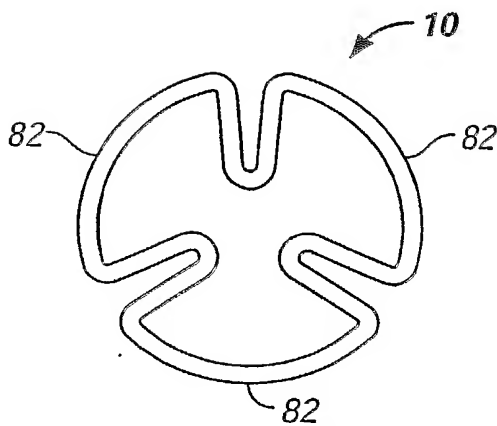


FIG. 13B

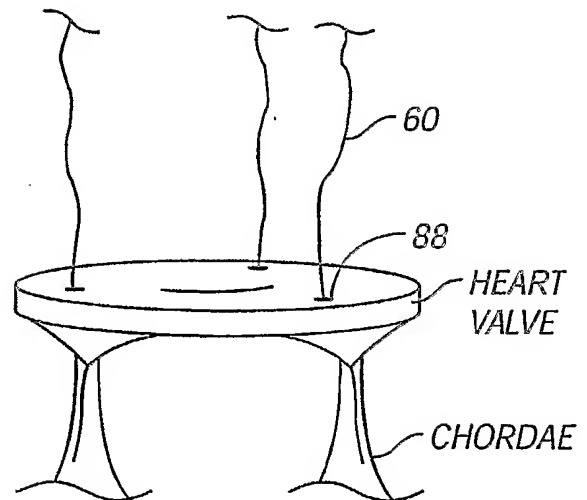


FIG. 14A

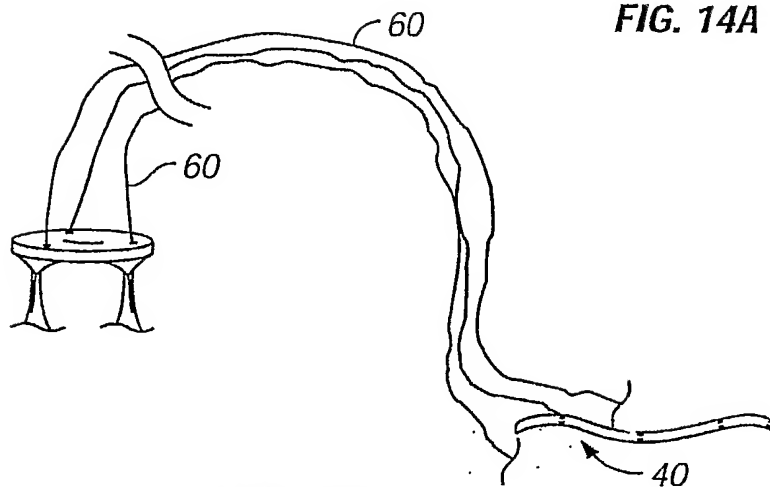


FIG. 14B

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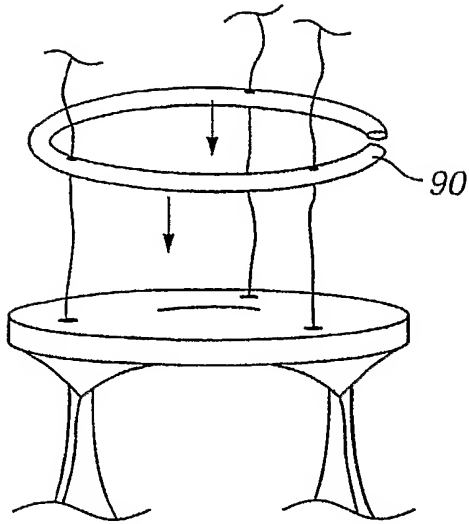


FIG. 14C

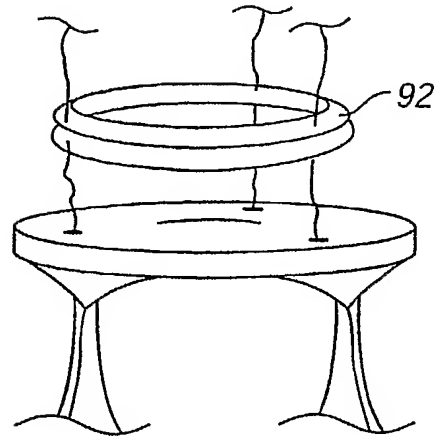


FIG. 14D

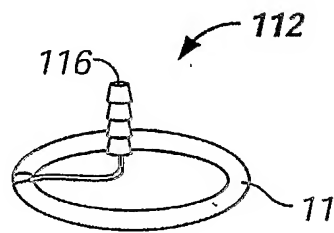


FIG. 15A

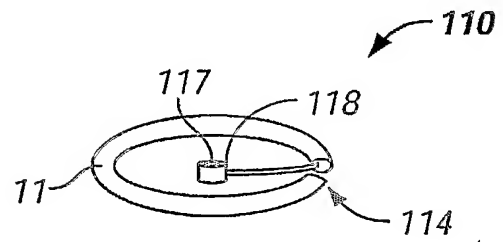


FIG. 15B

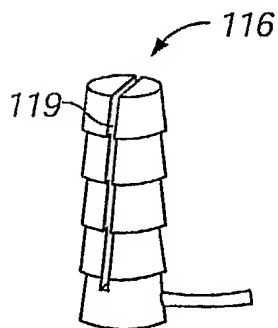


FIG. 16

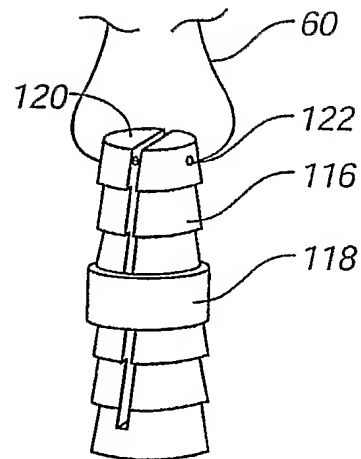


FIG. 17

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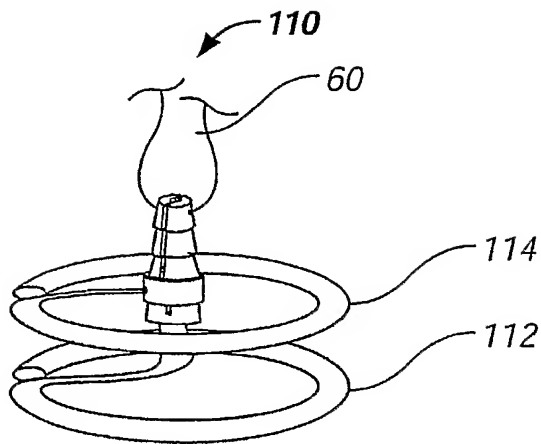


FIG. 18

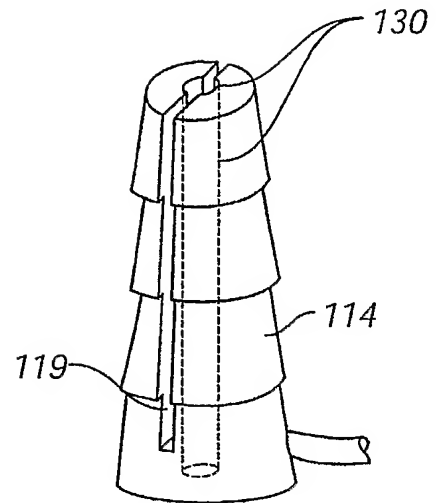


FIG. 19

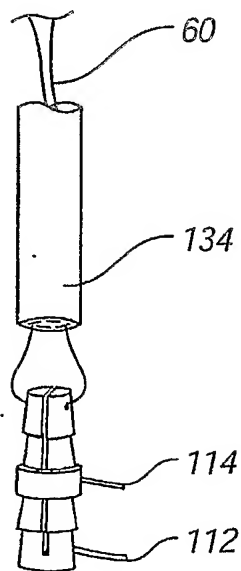


FIG. 20

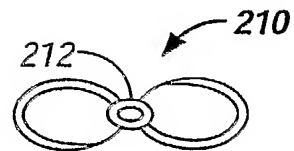


FIG. 21

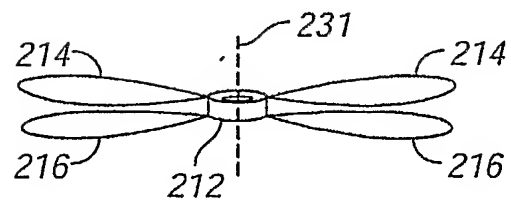


FIG. 22

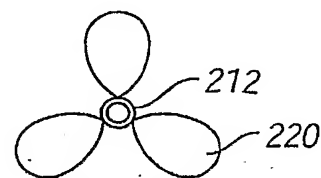


FIG. 23



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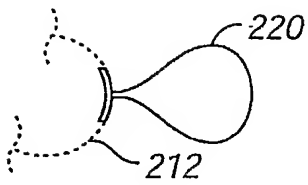


FIG. 24

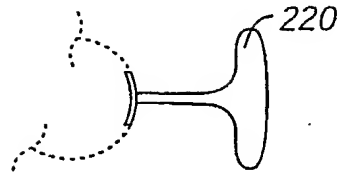


FIG. 25

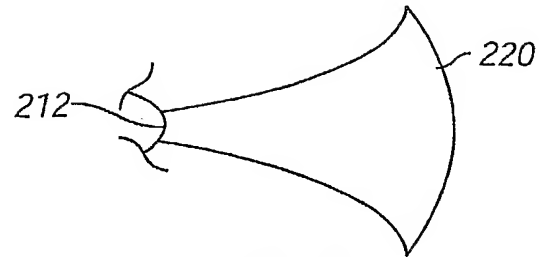


FIG. 26

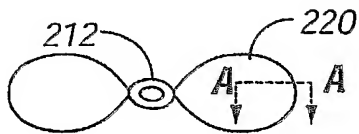


FIG. 27A



FIG. 27B



FIG. 27C

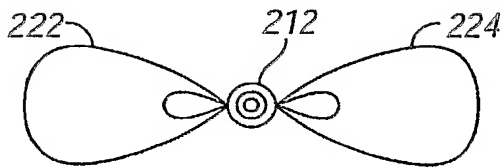


FIG. 27 D

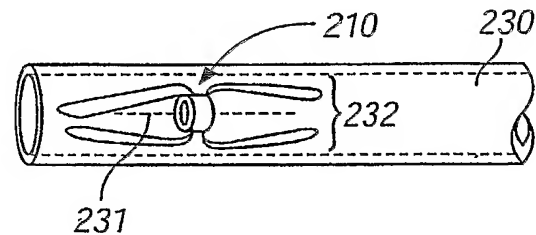


FIG. 28

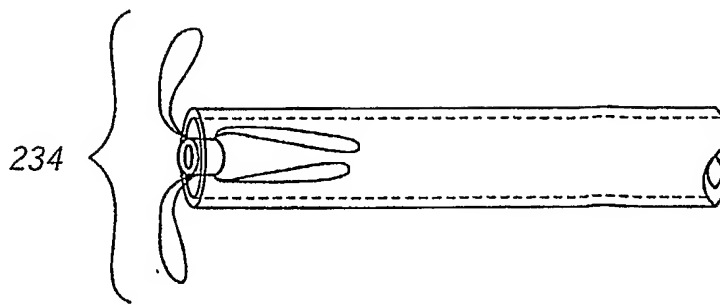
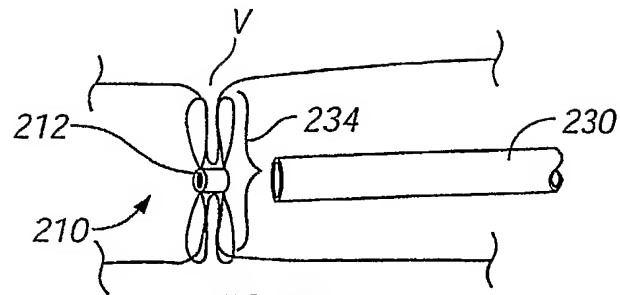
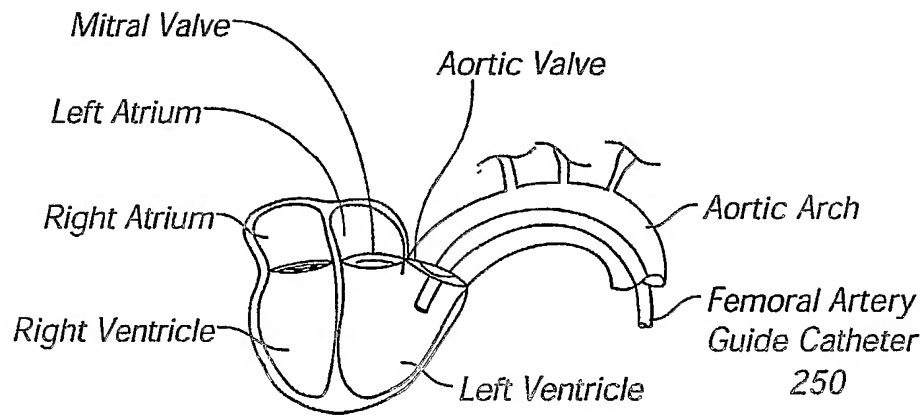
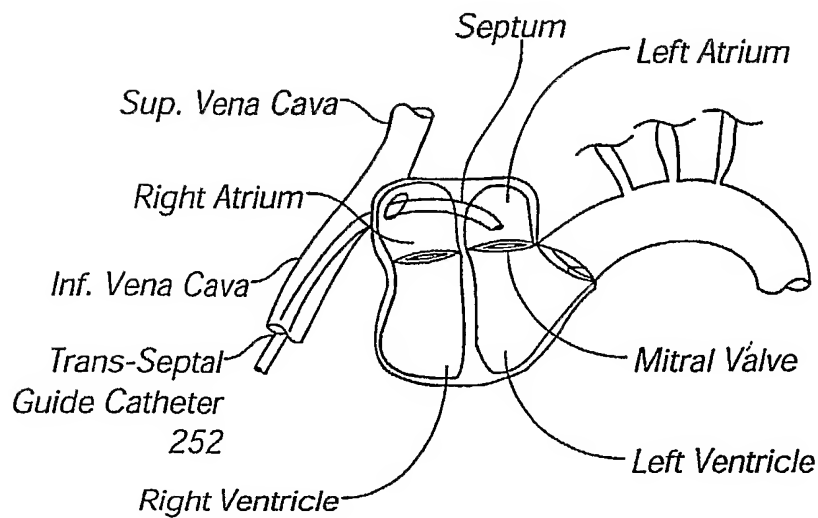


FIG. 29

**10/30****FIG. 30****FIG. 31****FIG. 32**

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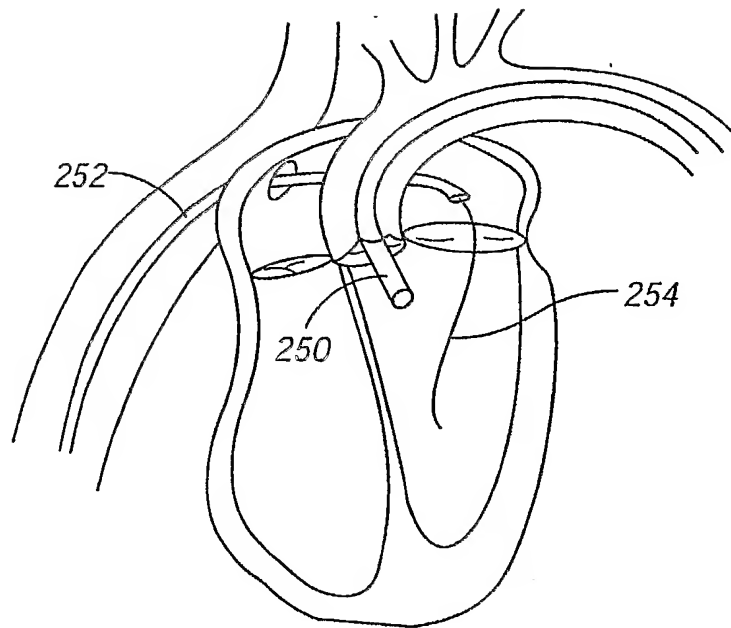


FIG. 33

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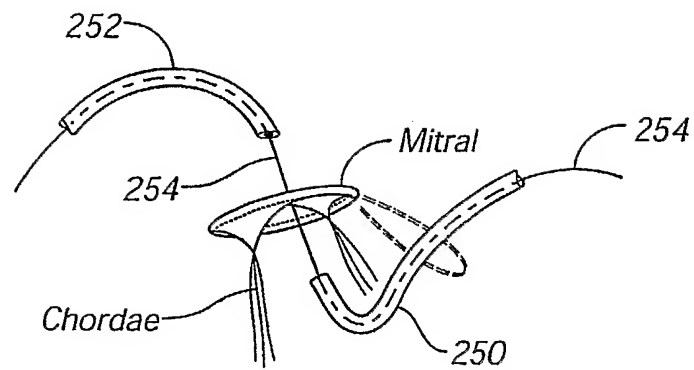


FIG. 34

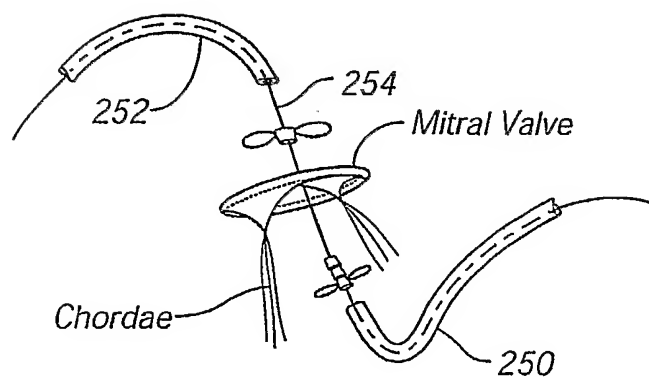


FIG. 35

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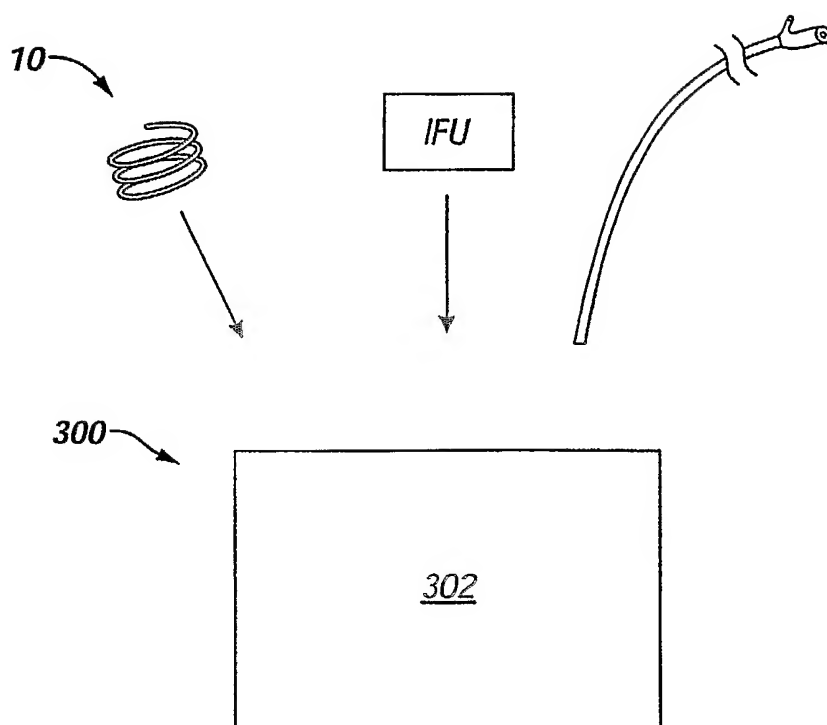
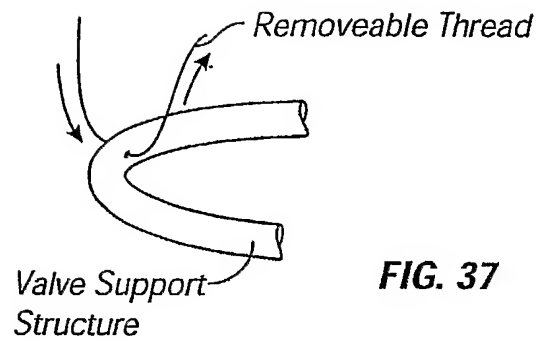
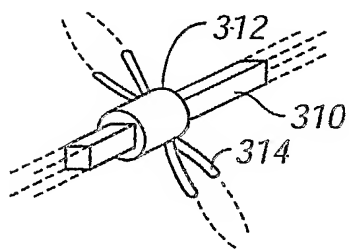


FIG. 36

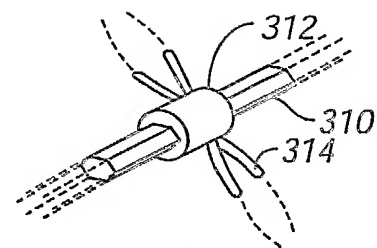
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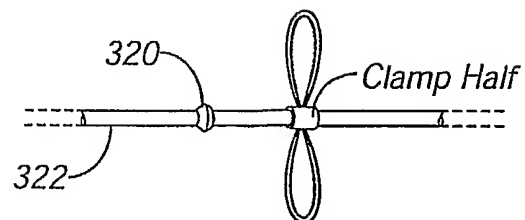
**FIG. 37**



**FIG. 38**



**FIG. 39**



**FIG. 40**

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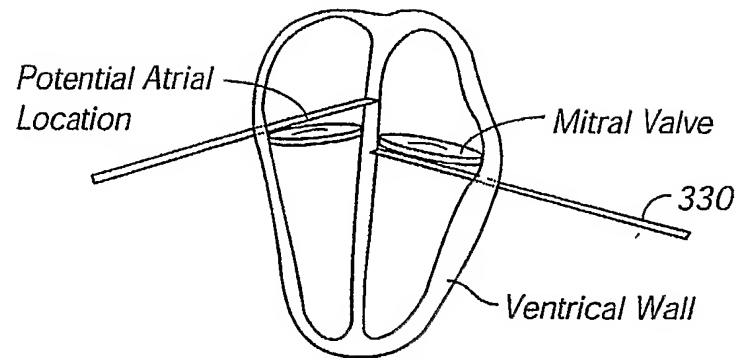


FIG. 41

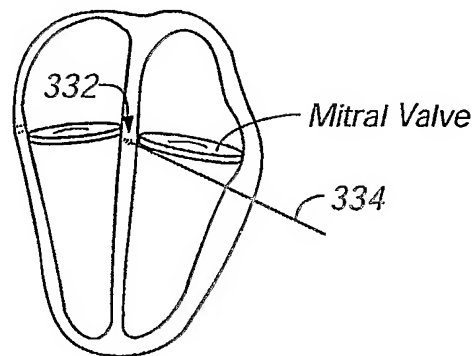


FIG. 42

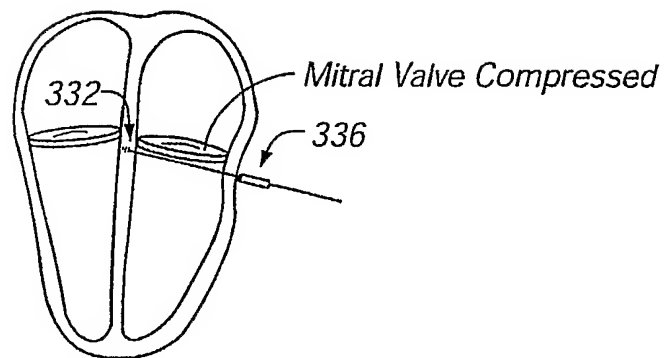


FIG. 43

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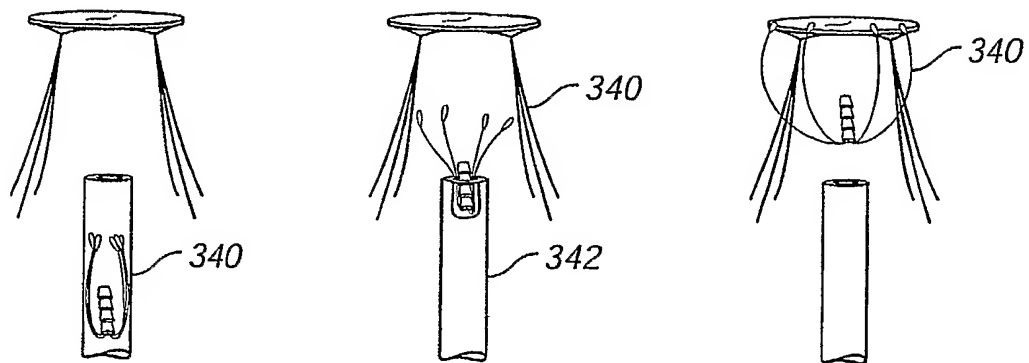


FIG. 44

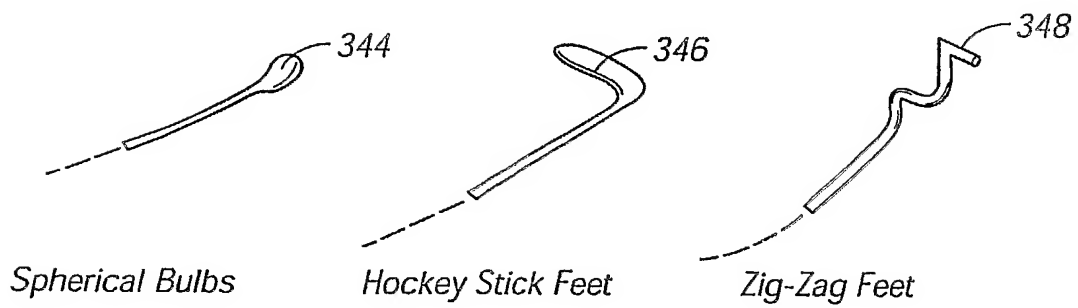


FIG. 45

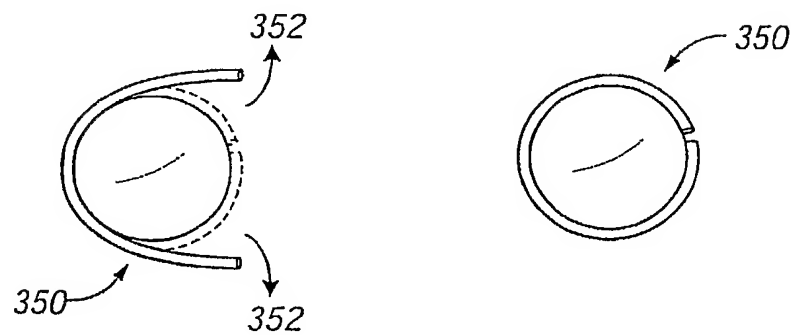


FIG. 46



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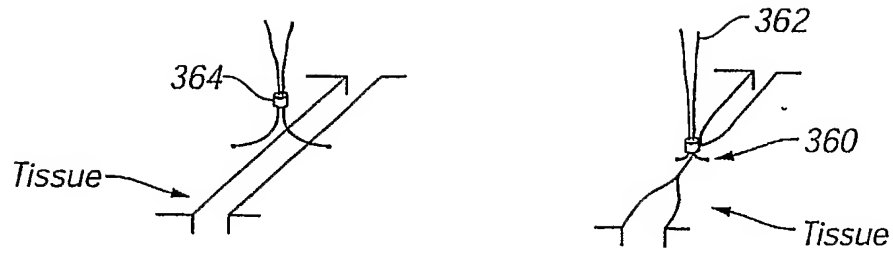


FIG. 47

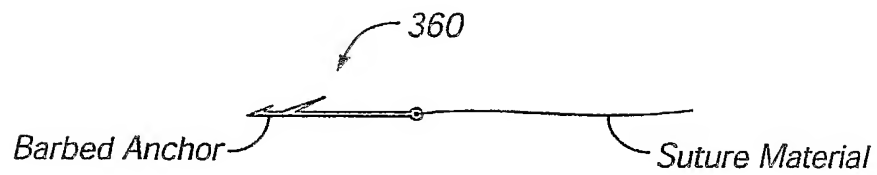


FIG. 48

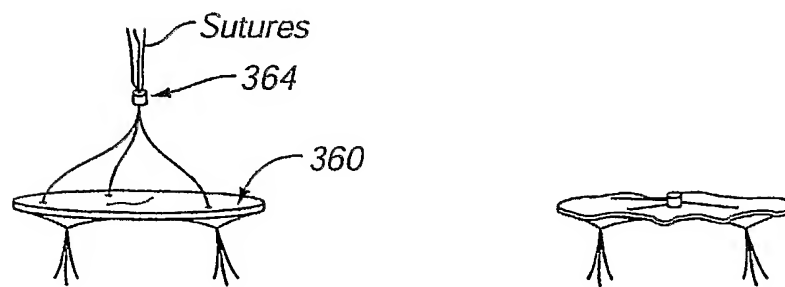


FIG. 49

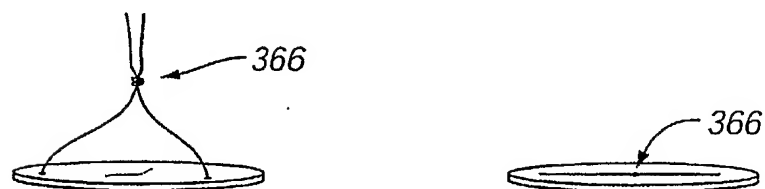


FIG. 50

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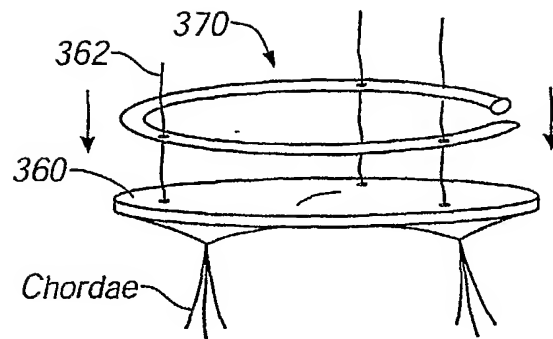


FIG. 51

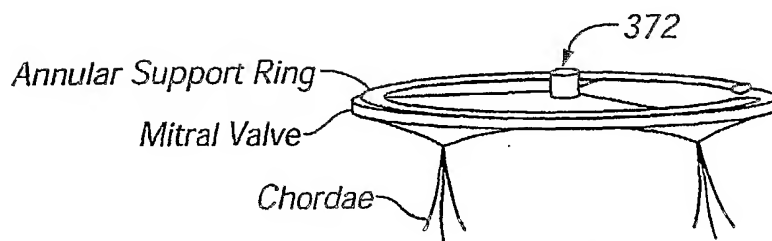


FIG. 52

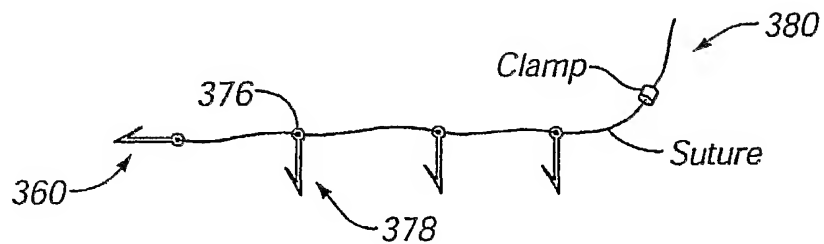


FIG. 53

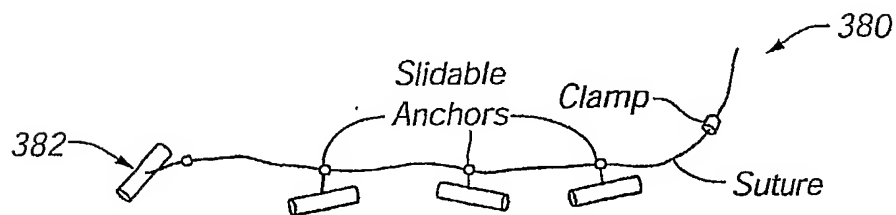


FIG. 54

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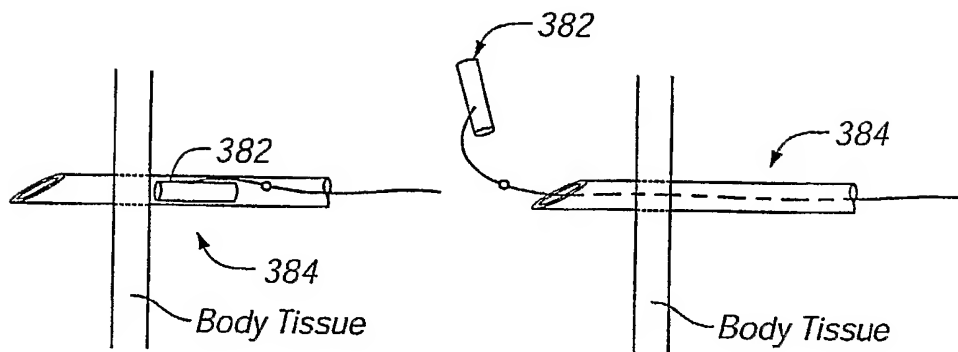


FIG. 55

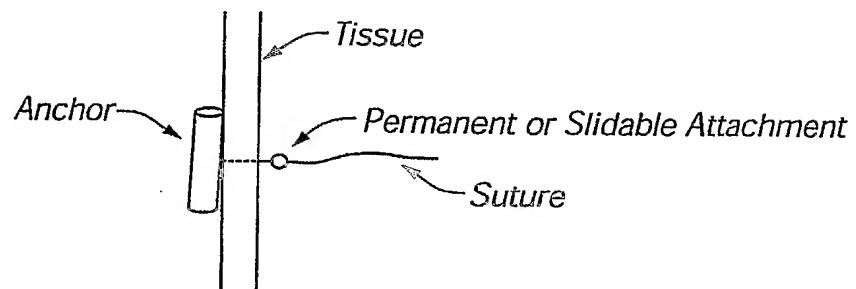


FIG. 56

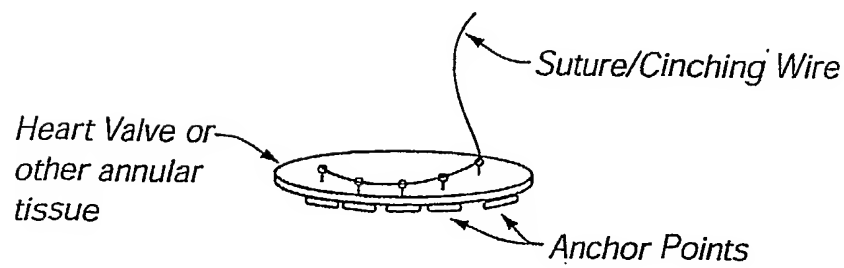


FIG. 57

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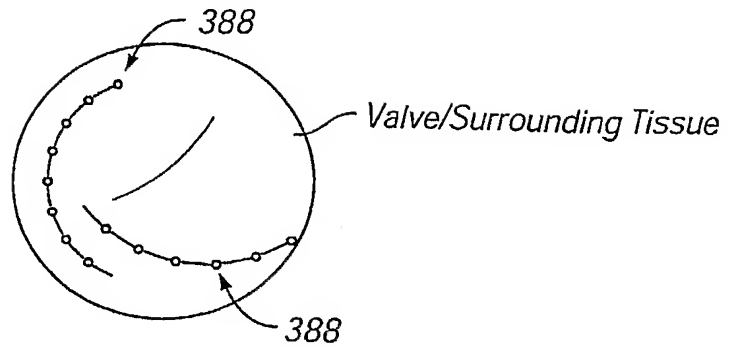


FIG. 58

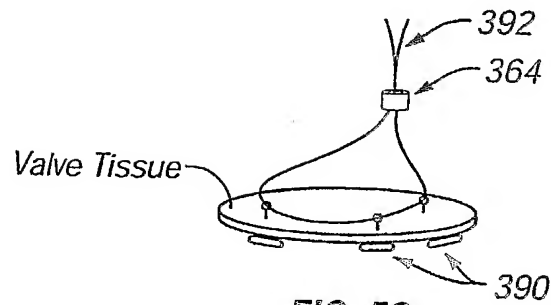


FIG. 59

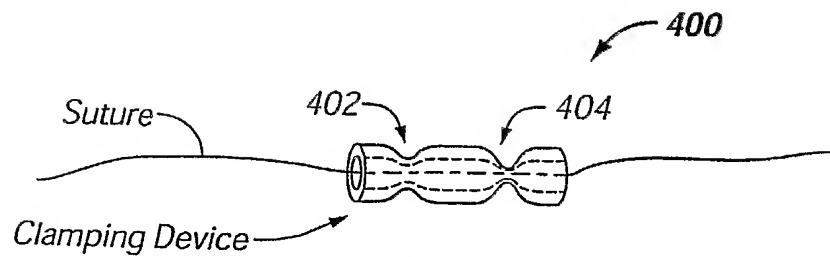


FIG. 60

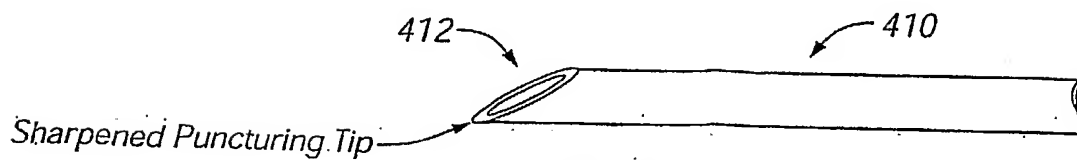


FIG. 61

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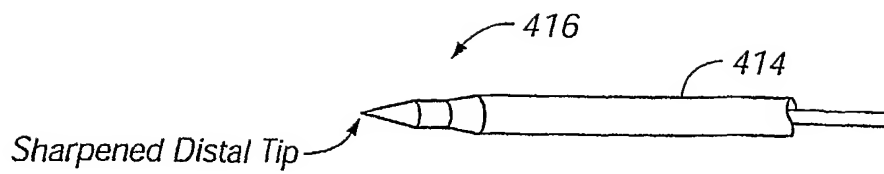


FIG. 62

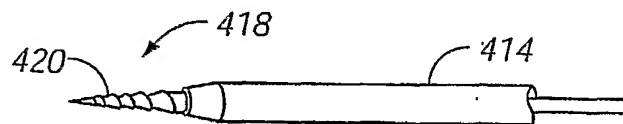


FIG. 63

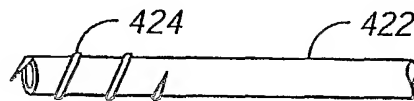


FIG. 64

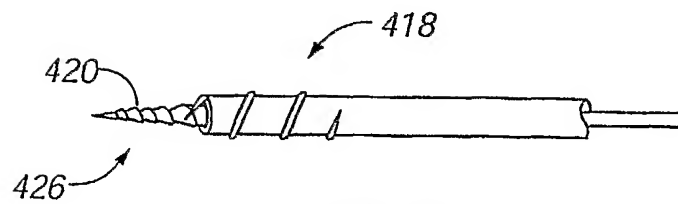


FIG. 65

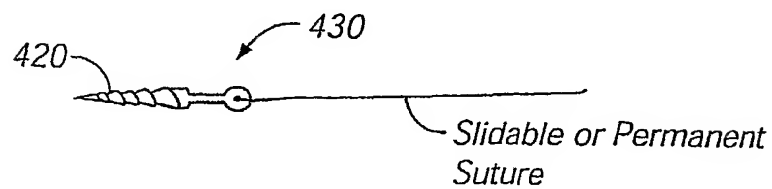


FIG. 66

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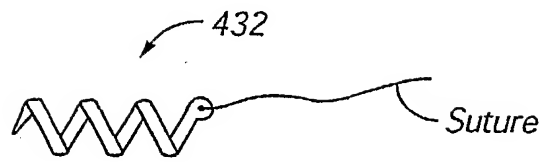


FIG. 67

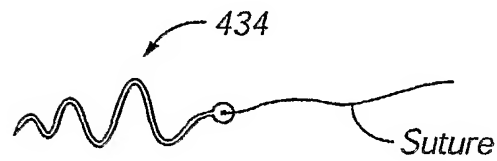


FIG. 68

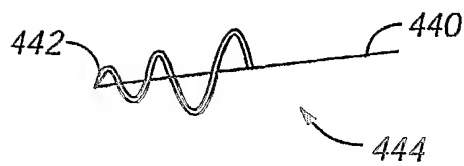


FIG. 69

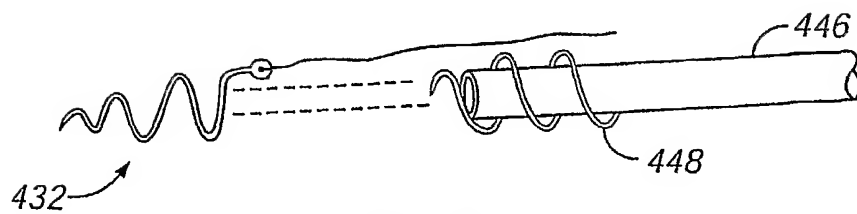


FIG. 70

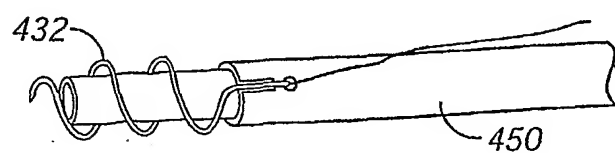


FIG. 71

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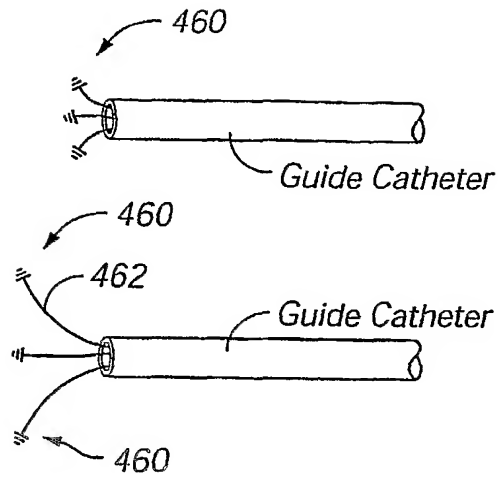


FIG. 72

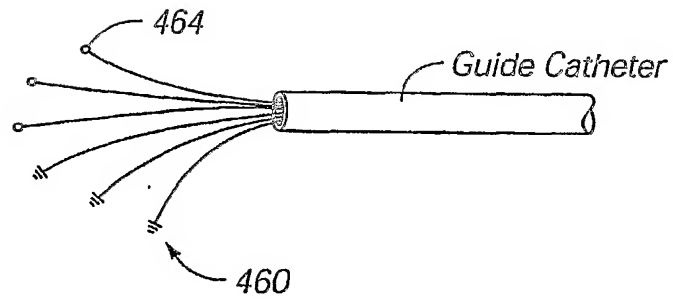


FIG. 73

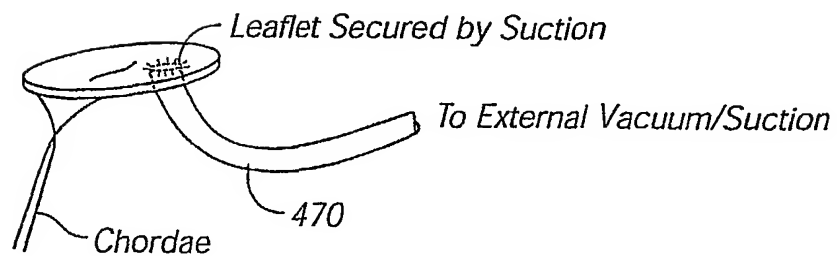


FIG. 74

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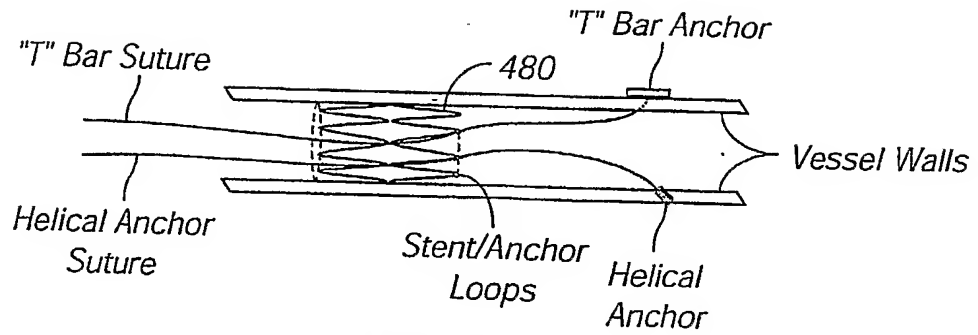


FIG. 75

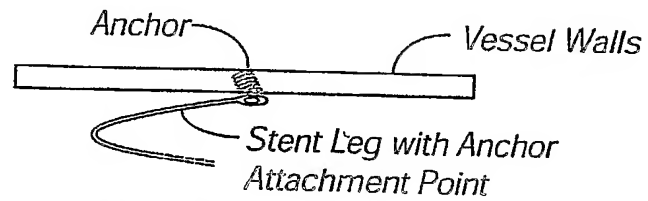


FIG. 76

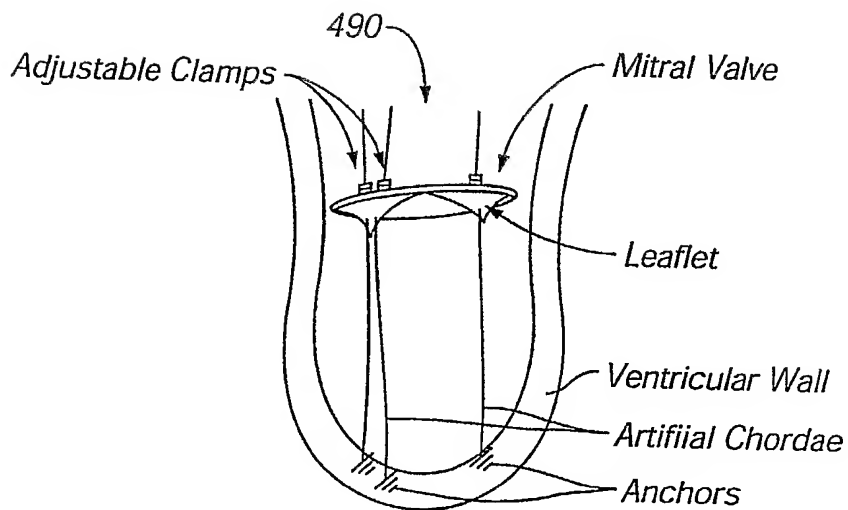


FIG. 77



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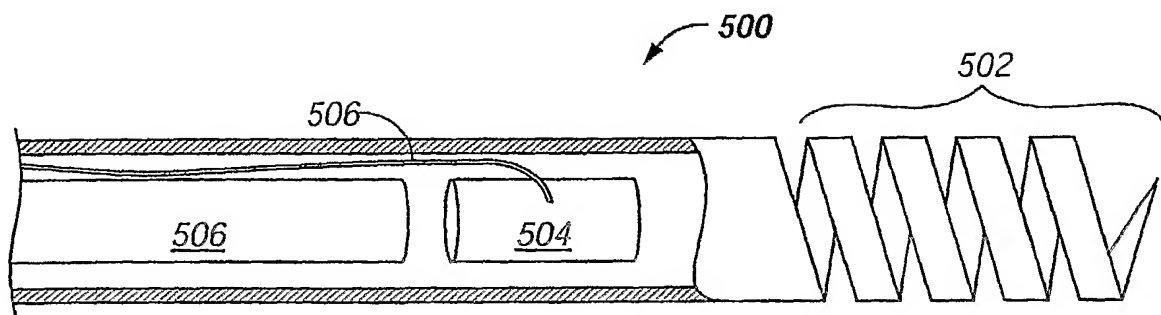


FIG. 78

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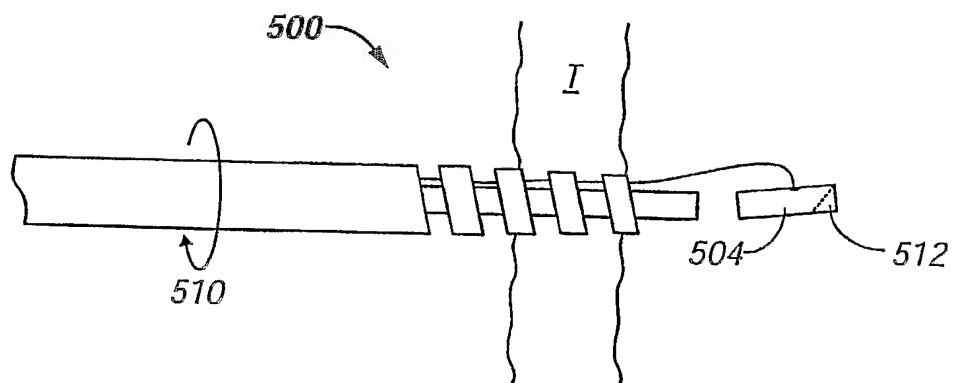


FIG. 79

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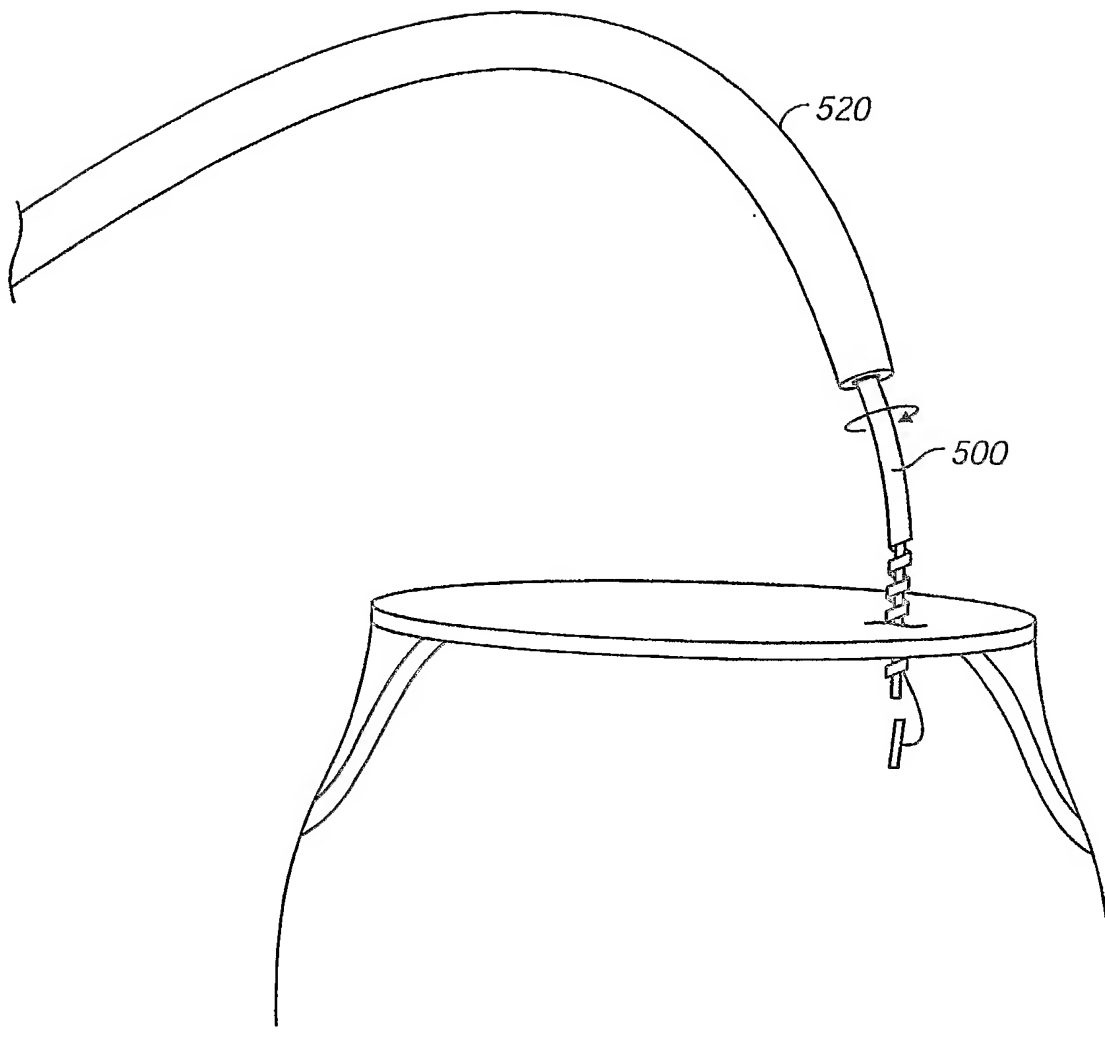


FIG. 80

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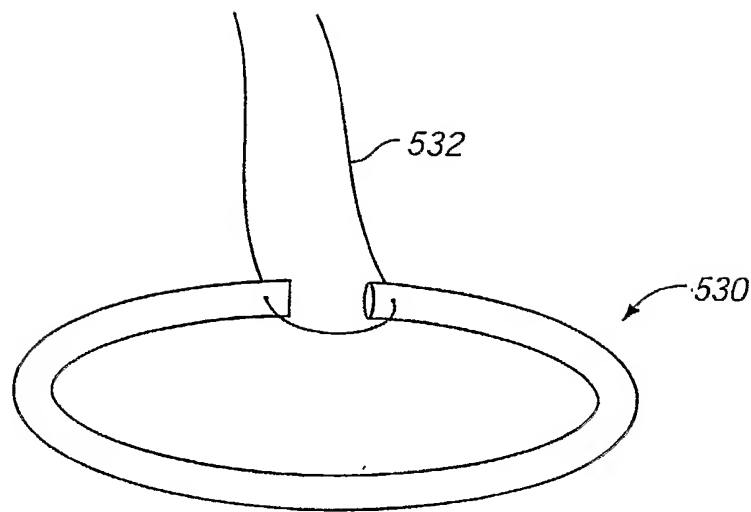


FIG. 81

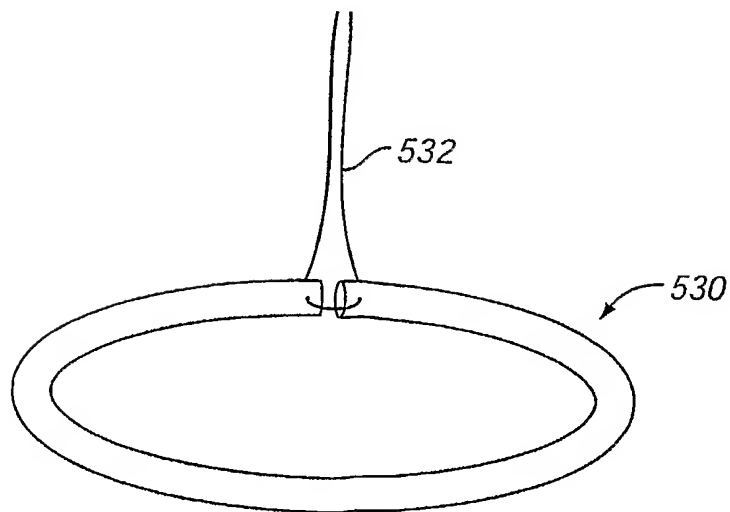
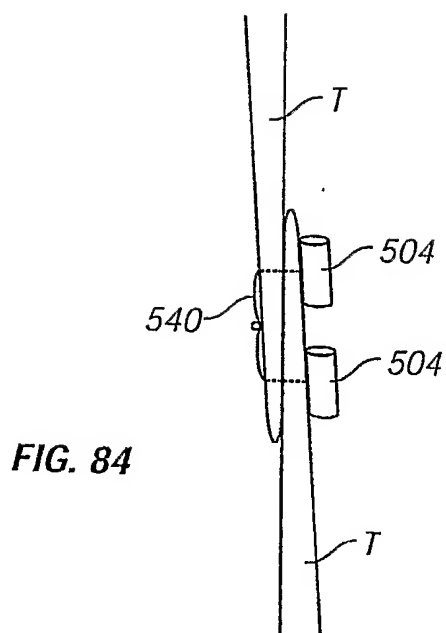
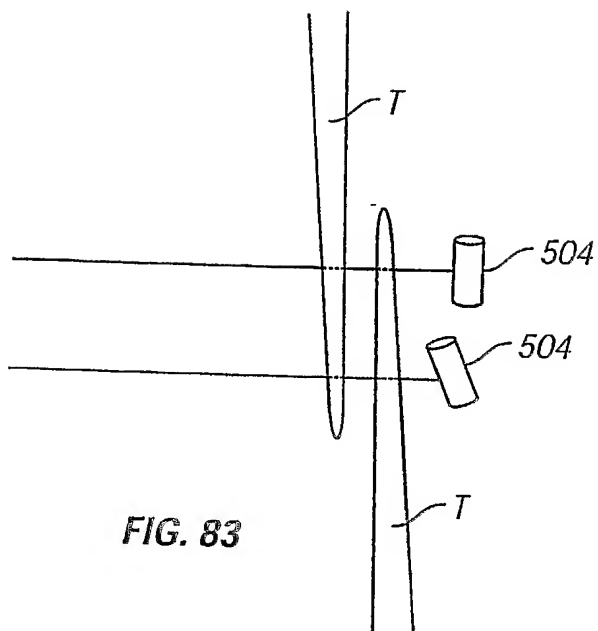


FIG. 82

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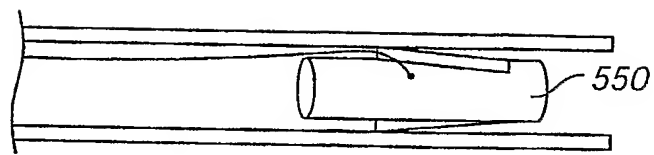


FIG. 85

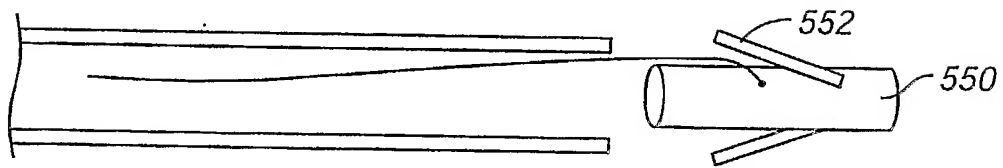
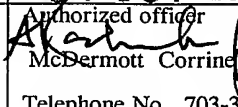


FIG. 86

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/18749

| <b>A. CLASSIFICATION OF SUBJECT MATTER</b>   |   |   |  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
|--|---|---|--|--|-----|---|-----|--|-----|--|-----|---|-----|--|-----|---|-----|---|-----|--|--|--|-----|--|--|--|
| IPC(7) : A61B 17/00; A61F 2/02   |   |   |  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| US CL : 606/213; 623/2.11  |   |   |  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| According to International Patent Classification (IPC) or to both national classification and IPC  |   |   |  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| <b>B. FIELDS SEARCHED</b>  |   |   |  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| Minimum documentation searched (classification system followed by classification symbols)<br>U.S. : 606/213; 623/2.11  |   |   |  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  |   |   |  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)   |   |   |  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| <b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>  |   |   |  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| Category *   | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No.   |  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| Y,E  | US 6,595,911 B2 (LOVUOLO) 22 July 2003 (22.07.2003), see columns 3-14.  | 1-16  |  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| Y  | US 6,290,674 B1 (ROUE et al.) 18 September 2001 (18.09.2001), see columns 3-16.   | 1-16  |  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| Y  | US 5,871,501 A (LESCHINSKY et al.) 16 February 1999 (16.02.1999), see columns 2, and 4-14.  | 1-16  |  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| Y  | US US 5,876,373 A (GIBA et al.) 02 March 1999 (02.03.1999), see columns 5-16.   | 1-16  |  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| Y  | US 5,477,864 A (DAVIDSON) 26 December 1995 (26.12.1995), see columns 5-14.  | 1-16  |  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| Y  | US 5,441,517 A (KENSEY et al.) 15 August 1995 (15.08.1995), see columns 4-15.   | 1-169   |  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| <input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.  |   |   |  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| <table border="0"> <tr> <td colspan="2">* Special categories of cited documents:</td> <td>"T"</td> <td>later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"A"</td> <td>document defining the general state of the art which is not considered to be of particular relevance</td> <td>"X"</td> <td>document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"E"</td> <td>earlier application or patent published on or after the international filing date</td> <td>"Y"</td> <td>document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"L"</td> <td>document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"&amp;"</td> <td>document member of the same patent family</td> </tr> <tr> <td>"O"</td> <td>document referring to an oral disclosure, use, exhibition or other means</td> <td></td> <td></td> </tr> <tr> <td>"P"</td> <td>document published prior to the international filing date but later than the priority date claimed</td> <td></td> <td></td> </tr> </table> |   |   | * Special categories of cited documents:   |  | "T" | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention | "A" | document defining the general state of the art which is not considered to be of particular relevance | "X" | document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone | "E" | earlier application or patent published on or after the international filing date | "Y" | document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art | "L" | document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "&" | document member of the same patent family | "O" | document referring to an oral disclosure, use, exhibition or other means |  |  | "P" | document published prior to the international filing date but later than the priority date claimed |  |  |
| * Special categories of cited documents:   |   | "T"   | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| "A"  | document defining the general state of the art which is not considered to be of particular relevance  | "X"   | document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone   |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| "E"  | earlier application or patent published on or after the international filing date   | "Y"   | document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| "L"  | document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "&"   | document member of the same patent family  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| "O"  | document referring to an oral disclosure, use, exhibition or other means  |   |  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| "P"  | document published prior to the international filing date but later than the priority date claimed  |   |  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| Date of the actual completion of the international search<br>12 August 2003 (12.08.2003)   |   | Date of mailing of the international search report<br><b>30 OCT 2003</b>  |  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US<br>Commissioner for Patents<br>P.O. Box 1450<br>Alexandria, Virginia 22313-1450<br>Facsimile No. (703)305-3230   |   | Authorized officer<br><br>McDermott Corrine<br>Telephone No. 703-308-0858 |  |  |     |   |     |  |     |  |     |   |     |  |     |   |     |   |     |  |  |  |     |  |  |  |